Supreme Court, U.S.
FILED
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No.

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1995

ERROL PAYNE, RICHARD PENFIL,
MEDSTONE INTERNATIONAL, INC. AND WEEDEN & CO., L.P.
Petitioners,
v.
WILLIAM KAPLAN, THOMAS DEVERE, AND
GEORGIANE KRAMER,
Respondents

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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QUESTIONS PRESENTED

1. In a class action under Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5, what standard should apply to determine when stock sales by corporate executives, standing alone, constitute circumstantial evidence sufficient to raise a triable issue on the question of scienter?

2. Under Section 11 of the Securities Act, are companies under an affirmative duty to disclose data regarding clinical trials, "however preliminary," prior to the completion of those trials?

DISCLOSURE PURSUANT TO RULE 29.1

Petitioner Medstone International, Inc. is now known as Cytocare, Inc.

Petitioner Weeden & Co., L.P. is a limited partnership with Weeden Securities Corp. as the general partner. No corporations serve as limited partners.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit, affirming in part and reversing in part the district court's grant of summary judgment for petitioners, is reported at 49 F.3d 1363, and is reprinted as Appendix A, at page A1. (References to the appendices bound with this Petition are styled ("A___")). The memorandum decision and order of the United States District Court for the Central District of California, from which appeal was taken, is reprinted as Appendix B, at page A34.

JURISDICTION

The decision of the court of appeals issued on October 11, 1994. A timely petition for rehearing and suggestion for rehearing *en banc* was denied on February 9, 1995. *See* Appendix C, at page A83. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 11 of the Securities Act of 1933, 15 U.S.C. § 77k (1988), provides in relevant part:

> Section 11. Civil Liabilities on Account of False Registration
>
> a. In case any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading, any person acquiring such security (unless it is proved that at the time of such acquisition he knew of such untruth or omission) may, either at law or in equity, in any court of competent jurisdiction, sue—
>
> (1) every person who signed the registration statement;
>
> (2) every person who was a director of (or person performing similar functions), or partner in, the issuer

at the time of the filing of the part of the registration statement with respect to which his liability is asserted;

(3) every person who, with his consent, is named in the registration statement as being or about to become a director, person performing similar functions, or partner;

(4) every accountant, engineer, or appraiser, or any person whose profession gives authority to a statement made by him, who has with his consent been named as having prepared or certified any part of the registration statement, or as having prepared or certified any report or valuation which is used in connection with the registration statement, with respect to the statement in such registration statement, report, or valuation, which purports to have been prepared or certified by him;.

(5) every underwriter with respect to such security.

Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), provides in relevant part:

Section 10. Regulation of the Use of Manipulative and Deceptive Devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange—

(b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

Securities and Exchange Commission Rule 10b-5, 17 C.F.R. 240.10b-5, provides.

10b-5. Employment of Manipulative and Deceptive Devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails, or of any facility of any national securities exchange—

i) to employ any device, scheme or artifice to defraud,

ii) to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

iii) to engage in any act, practice or course of business which operates or would operate as a fraud or deceit upon any person,

in connection with the purchase or sale of any security.

STATEMENT OF THE CASE

I. Events Prior to the Commencement of Suit

Medstone was formed in 1984 to develop a system for treating kidney stones with the non-invasive use of shockwaves, a process known as "lithotripsy." In August 1986, the U.S. Food and Drug Administration approved clinical studies to evaluate Medstone's lithotripsy system for treating kidney stones. In April 1988, as a result of the success of these trials, the FDA gave Medstone approval to sell its system in the United States for the treatment of patients with kidney stones. In January 1988, the FDA also gave Medstone permission to commence clinical studies regarding the system's use for the treatment of patients with gallstones. If Medstone received FDA approval for the system's use on gallstones, it would have made Medstone's machine the only one that could be used on both kidney stones and gallstones. (A35). It was anticipated that this dual use would enable Medstone's system to achieve substantial market success. *Id.*

In June 1988, Medstone went public through an initial public offering ("IPO"). In the accompanying prospectus, Medstone explained that the FDA had authorized clinical trials for the treatment of gallstones at several locations in the United States, but that, as of the time of the prospectus, installation had been completed at only one of these hospitals (at Baylor University).

(Prospectus at 19). The prospectus further explained that even at Baylor, the procedure so far only had been used "on a limited number of patients." (*Id.* at 6). Although more persons suffer from gallstones than from kidney stones, the prospectus cautioned that "it is anticipated that the percentage of persons who have gallstones that will be susceptible to treatment will not be as high as those with kidney stones," and that "the percentage of lithotripsy-treatable patients is not presently known." (*Id.* at 16). The prospectus stated that "an objective of the clinical studies to be conducted . . . will be to develop information on this subject." (*Id.*).

In describing Medstone's competition, the prospectus noted that Dornier Medizintechnik GmbH ("Dornier"), a part of the Daimler Benz group, was presently the dominant supplier in the sale of shockwave lithotripters for kidney stones. The prospectus also informed prospective investors that a Dornier machine designed to treat gallstones had "been used successfully to treat over 175 [gallstone] patients in Europe," and that Dornier had received FDA approval to commence clinical trials on this gallstone lithotripter. (*Id.* at 22).

In September 1988, three months after the IPO, Medstone's Chief Executive Officer ("CEO"), Errol Payne, resigned from the company, and concurrently sold two-thirds of his stock in Medstone. Dr. Richard Penfil, the company's President, also sold approximately one-quarter of his stock in the fall of 1988. Six months later, in March 1989, several physicians participating in the Medstone clinical trial (including both FDA monitors) submitted an article to a prestigious medical journal documenting preliminary results of the study. These results were comparable to those reported in the German Dornier study the previous year.[1]

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[1] In the study involving the Dornier machine conducted in Germany, an article was published in February 1988 reflecting the results that had been achieved on the first 175 patients out of 565 patients selected to be treated. *See* Michael Sackmann et al., *Shock-Wave Lithotripsy of Gallbladder Stones (The First 175 Patients)*, 318 N. Eng. J. Med. 393 (1988). The study was designed to test only those patients with 3 or fewer gallstones, a criterion which excluded several hundred potential patients (approximately 44% of those initially referred to the study). *Id.* at 393. The Dornier study reported that initial results were significantly

In May 1989, the FDA division director with oversight responsibility for the approval process indicated at a medical conference that she expected gallstone lithotripsy to be approved within a year. (A65). An internal memorandum from Dr. Penfil to Freeman Rose, Medstone's new CEO, reported regarding a June 1989 meeting with the FDA that "[t]he meeting with the FDA was extremely beneficial and I feel, . . . [it] could not have come out better for Medstone." (A65). Two months later, in August 1989, Dr. Penfil resigned from the company, citing concerns for his health (which concerns were subsequently realized), and sold his remaining shares in Medstone.

On October 20, 1989, the FDA announced that it would not approve the application of either Medstone or Dornier for the treatment of gallstones with shockwave lithotripsy. (A3). The price of Medstone's stock responded by dropping from approximately $12 to approximately $6. *Id.* Medstone CEO Freeman Rose, who owned 100,000 Medstone shares, and David Radlinski, Medstone's Chief Financial Officer, who also owned stock, did not sell any Medstone stock during this period. The company's

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better for those patients with 1 stone under 20 millimeters than for those with multiple stones or with a stone greater than the size. *Id.* at 395. At the time the article was submitted, results showed that those with 1 stone under 20 millimeters were likely to be stone-free at a rate of 45% within 2 months; 69% at 2-4 months; and 78% at 4-8 months. *Id.*

In March 1989, a similar article was submitted for publication by 12 of the principal physicians involved on the results that they had obtained for the first 223 patients in the 600-patient Medstone trial. *See* David Burnett et al., *Use of External Shock-Wave Lithotripsy and Adjuvant Ursodiol for Treatment of Radiolucent Gallstones (A National Multicenter Study)*, 34 Digestive Diseases & Sci. 1011 (1989). Unlike the Dornier study, the Medstone study did not exclude patients with more than three gallstones. *Id.* at 1012. The reporting physicians nonetheless found that "the results reported here are in excellent agreement with those reported by Sackmann et al." *Id.* at 1014. In particular, for patients with 1 stone of less than 20 millimeters, their stone-free rates were reported at that time as 54% after 3 months, and 90% after 6 months. *Id.* at 1011. (As discussed *infra*, these results were subsequently revised downwards based on results as of the time the article was proofed prior to its July 1989 publication to an estimated 51% stone-free rate at 6 months.)

vice president of marketing and one of its outside directors purchased Medstone stock in October 1989 just prior to the FDA's decision. Declaration of Mark Cherney ¶ 4; Declaration of J. Donald Hill ¶ 9.

II. Proceedings in the District Court

Five days after Medstone's October 20, 1989 announcement, plaintiffs filed a shareholder class action against Medstone and Payne, Penfil, Rose, Radlinski and Weeden & Co., the underwriters for the initial public offering, alleging violations of Section 11 and Section 10(b) of the Securities Exchange Act of 1934.

After two years of voluminous discovery, the defendants filed a motion for summary judgment as to the 51 ostensibly actionable "statements" (many of which consisted of lengthy passages or even entire financial statements) identified in the plaintiffs' 106-page Second Amended Complaint. By way of their own motion for summary adjudication, plaintiffs sought to add yet more statements that were not included in the Complaint. The district court, treating plaintiffs' motion as a belated motion to amend, declined to consider these additional statements. (A40-A43).

The district court granted defendants' summary judgment motion on both Section 10(b) and Section 11. With respect to plaintiffs' Section 10(b) claim, the district court found, *inter alia*, that the plaintiffs had failed to raise a triable issue as to the defendants' scienter. The district court noted that the four individual defendants had filed declarations stating that they had a good faith belief that each of the statements identified by plaintiffs was true at the time it was made. The district court also found that the defendants' contemporaneous actions were consistent with this belief: they "moved operations to a bigger, more expensive site in May 1989; they increased the size of their inventory until October 1989 and correspondingly increased their number of personnel; and the company entered into an international distribution agreement with GE [in December of 1988]." (A65). In addition to the positive indications that the company had received from the FDA in May and June 1989 regarding the likelihood of gallstone approval, the district court noted the deposition testimony of one of Medstone's regulatory experts, a

former FDA division director, that he had informed Medstone at meetings in the spring and in August 1989 that he believed Medstone's gallstone application would be approved. (A64-A65).

In responding to this showing by the defendants, the district court noted that plaintiffs had pointed to only one basis for claiming that a triable issue existed on this essential element: the fact that two of the four individual defendants had sold stock during the lengthy class period. The district court found that the timing of these sales would not support an inference of scienter. Two of the sales had occurred concurrently with the officers' resignation from the company, which provided a "credible and wholly innocent explanation[ ] for the stock sale," (A65), while the remaining sale occurred more than a year before the FDA made its decision.

The district court also rejected plaintiffs' Section 11 claim, finding that the defendants had no duty to disclose in the June 1988 prospectus information regarding results to date of the gallstone clinical trials. The court found such information, which was limited to one hospital and only a handful of patients, too speculative to give rise to a duty to disclose. (A34). The district court also rejected plaintiffs' claim that statements in the prospectus that the Medstone machine had been used "successfully" on gallstones since January 1988 were misleading without the disclosure of this information. The district court found that these statements were not misleading in context, in that the prospectus had made clear that treatment had commenced at only one hospital, only involved a limited number of patients, had been underway for only a limited period of time, and was applicable to an unknown percentage of gallstone patients (estimates of patient eligibility ranged at the time from 2% to 70%). (A58).

III. Proceedings in the Court of Appeals

The Ninth Circuit reversed the district court's entry of summary judgment on the Section 10(b) claim as to defendants Medstone, Payne, Penfil, and Weeden & Co. The court of appeals acknowledged that the defendants had submitted direct evidence of their good faith that, if uncontroverted, was sufficient to support the entry of summary judgment. It also agreed with the district court that Medstone had introduced additional circum-

stantial evidence supporting its claim that the defendants had acted in good faith, and that the sole admissible evidence proffered by plaintiff were the defendants' stock sales. (A23-A26). Because Messrs. Rose and Radlinski did not sell any stock, the court of appeals affirmed the entry of summary judgment as to these defendants. As to defendants Payne and Penfil, however, the court found that their sales of stock, standing alone, raised a sufficient factual dispute requiring them to proceed to trial for securities fraud under Section 10(b). Summary judgment for Weeden & Co. was reversed solely because a Weeden employee, Don Hill, sat on Medstone's board of directors, (A27-A28), even though Mr. Hill submitted an affidavit of good faith and had purchased Medstone stock during the class period.

Noting the standard from prior decisions that stock trades "in suspicious amounts or at suspicious times" are probative of scienter, the court found that liquidation of an executive's holdings upon departure from a company constitutes a "suspicious amount" of trading. (A25). As for the timing of the trades, the court of appeals concluded that their timing did raise "suspicions" in that they occurred "at times alleged to have been calculated to avoid the negative effects of undisclosed inside information." (A25). Not surprisingly, since a class period by definition is the period during which there is alleged to be "undisclosed inside information," the court of appeals found that the trades by Messrs. Payne and Penfil satisfied that standard. The court of appeals also rejected the defendants' argument that the desire to sell one's stock upon departure from the company constitutes an alternative "credible and wholly innocent" explanation for the sales. The court of appeals concluded that this explanation "merely beg[s] the question of whether they acted on the basis of undisclosed inside information in order to reap large returns." (A26).

The court of appeals also reversed the entry of summary judgment on plaintiffs' Section 11 claim, on the ground that the defendants were under a duty to disclose first-day results for an initial group of patients in a study designed to measure results for a much larger group over a six-month period. The court of appeals found two separate bases for this duty. First, the court of appeals concluded that two statements in the prospectus poten-

tially were misleading without this information — information which the court believed might lead an investor to believe that the Dornier machine performed better than Medstone's.

Second, even apart from the prospectus statements, the court apparently recognized an affirmative duty to disclose clinical trial information, "however preliminary."[2] (A14-A16). In so holding, the Ninth Circuit did not limit its ruling to results that were statistically significant, or that were otherwise extraordinary (as, for example, that showed substantial mortality rates that might require early termination of the test). Rather, the court's determination apparently was that all such results might have to be disclosed. The court reasoned that such information is "harder data" than, for example, corporate forecasts, and that the information "was not trivial," which the court viewed as this Court's principal concern in *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988). (A15).

Under both its "incomplete disclosure" and "material omission" theories, the court of appeals applied a standard for materiality that this Court in *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438 (1976), expressly rejected in the Section 14(a) context, namely, that the information was material if it "might" have affected the stock-purchasing decision of a reasonable investor. (A16). The court did not address how its holding could be reconciled with FDA practice restricting the disclosure of clinical information.

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[2] Having engaged in a lengthy analysis why it believed the omitted information may have rendered the statements in the prospectus misleading, and why such information might have been material (A10-A15), the court then addressed, under a separate section heading, whether the defendants had a duty to disclose the clinical results. The court's analysis is undertaken in terms of whether there is an affirmative duty to disclose, and any other reading would appear to render this section of the court's opinion superfluous.

REASONS FOR GRANTING THE WRIT

I. The Court Should Determine When Stock Sales Constitute Sufficient Evidence of Scienter to Defeat Summary Judgment on a Section 10(b) Claim.

Section 10(b) class actions recently have been the subject of enormous congressional and scholarly attention because of the tremendous burden that they place on American business. In such suits, plaintiffs now principally rely upon stock sales by officers or directors during the class period to argue that they have shown circumstantial evidence of scienter sufficient to defeat summary judgment. The standard for determining when stock sales are sufficient to create a triable issue on scienter is in substantial disarray among the lower courts, as evidenced, *inter alia*, by the conflict between the Ninth Circuit's decision below and *Acito v. IMCERA Corp.*, 47 F.3d 47 (2d Cir. 1995).

The rule adopted by the Ninth Circuit in this case, like that reversed by this Court in the antitrust context in *Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574 (1986), has the perverse effect of deterring conduct that is socially beneficial. Recent economic analysis indicates that corporate performance, and hence shareholder value, are enhanced when executives have substantial stockholdings in the firm. Under the Ninth Circuit's rule, however, such compensation becomes highly illiquid, so that an executive even upon departing the firm cannot convert these stockholdings without facing securities litigation exposure. The resulting chilling effect on the willingness of executives to accept such compensation, despite the benefit to shareholders from such a compensation structure, supports adoption of a rule that — unlike the Ninth Circuit's here — is more consistent with public policy and in which the circumstances better justify drawing an inference of fraudulent intent.

A. *The Lower Courts Are in Disarray on this Critical Issue.*

In order to prevail on a claim under Section 10(b) and Rule 10b-5, a plaintiff must be able to show that the defendant acted with "scienter," *Ernst & Ernst v. Hochfelder*, 425 U.S. 185 (1976), which lower courts have interpreted to mean either an

intent to defraud or some species of recklessness. *See, e.g., Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1568-70 (9th Cir. 1990) (*en banc*), *cert. denied*, 499 U.S. 976 (1991); *Sunstrand Corp. v. Sun Chem. Corp.*, 553 F.2d 1033, 1045 (7th Cir.), *cert. denied*, 434 U.S. 875 (1977); *Rolf v. Blyth, Eastman, Dillon & Co.*, 570 F.2d 38, 47 (2d Cir.), *cert. denied*, 439 U.S. 1039 (1978). In the proliferation of Rule 10b-5 class actions in the 1980s and 1990s — according to one study, one out of every eight companies listed on the New York Stock Exchange was sued for securities fraud between 1988 and 1993[3] — plaintiffs have relied heavily on stock sales by corporate executives as providing circumstantial evidence of scienter.[4]

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[3] See *Proceedings and Debates on the Securities Litigation Reform Act*, 104th Cong., 1st Session, 141 Cong. Rec. H2857 (daily ed. Mar. 8, 1995) (remarks of Rep. Cox); *Hearings Before the Securities Subcommittee of the Senate Comm. on Banking, Housing & Urban Affairs*, 103d Cong., 1st Session (1993) (statement of Vincent E. O'Brien). As Senator Domenici observed during recent hearings on the Private Securities Litigation Reform Act of 1995:

> The list of companies that have been hit with frivolous securities suits reads like the who's who of high growth, high-technology businesses. In fact, 19 of the 30 largest companies in Silicon Valley have been sued since 1988. They are the backbone of our economy and the foundation of our ability to compete in the new global marketplace.

141 Cong. Rec. S1075 (daily ed. Jan. 18, 1995) (remarks of Sen. Domenici). *See also* Brent Bowers & Udayan Gupta, *Shareholder Suits Beset More Small Companies*, Wall St. J., Mar. 9, 1994, at B1 ("The class-action newsletter estimates that total cash settlements of shareholder class-action lawsuits . . . nearly quintupled to $1.55 billion in 1992 from $324 million in 1988").

[4] *See, e.g., In re Seagate Technology II Sec. Litig.*, 843 F. Supp. 1341, 1371-72 (N.D. Cal. 1994); *Searls v. Glasser*, No. 91-C-6796, 1994 U.S. Dist. LEXIS 13509, at *30-*31 (N.D. Ill. Sept. 23, 1994); *Provenz v. Miller*, [1994-1995 Tr. Binder] Fed. Sec. L. Rep. (CCH) ¶ 98,347, at 90,404 (N.D. Cal. June 27, 1994); *In re Healthcare Compare Corp. Sec. Litig.*, No. 93-C-1970, 1994 U.S. Dist. LEXIS 7304, at *30-*34 (N.D. Ill. June 1, 1994); *O'Sullivan v. Trident Microsystems, Inc.*, [1993-1994 Tr. Binder] Fed. Sec. L. Rep. (CCH) ¶ 98,116 at 98,912-13 (N.D. Cal. Feb. 2, 1994); *In re Exabyte Corp. Sec. Litig.*,

Plaintiffs' reliance on stock sales is, perhaps, not surprising, inasmuch as recent studies suggest that more than 90% of all companies offer stock options as a significant component of incentive compensation.[5] For younger growth companies, moreover, which are particularly attractive targets for shareholder suits because of their greater stock volatility,[6] management is likely to have a substantial equity stake in the company. Indeed, one recent study found that in a sample of firms engaged in initial public offerings, management at the time of the IPO on average owned more than 50% of the stock of the company.[7]

In any given period, therefore, the odds are very high that a plaintiff can find one or more officers who exercised their options

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823 F. Supp. 866, 869 (D. Colo. 1993); *In re Worlds of Wonder Sec. Litig.*, 814 F. Supp. 850, 871-72 (N.D. Cal. 1993), *aff'd in relevant part*, 35 F.3d 1407 (9th Cir. 1994); *Taponga v. Egan*, 141 F.R.D. 370, 373-74 (D. Mass. 1992); *Berliner v. Lotus Development Corp.*, 783 F. Supp. 708, 712 (D. Mass. 1992); *In re Cypress Semiconductor Sec. Litig.*, [1992 Tr. Binder] Fed. Sec. L. Rep. (CCH) ¶ 97,060 (N.D. Cal. Sept. 23, 1992); *Alfus v. Pyramid Technology Corp.*, 764 F. Supp. 598, 604-05 (N.D. Cal. 1991); *Halye v. Lamson & Sessions Co.*, 752 F. Supp. 822, 825-26 (N.D. Ohio 1990), *aff'd sub nom., Sinay v. Lamson & Sessions Co.*, 948 F.2d 1037 (6th Cir. 1991).

[5] *See* Patrick J. Straka, *Executive Compensation Disclosure: The SEC's Attempt to Facilitate Market Forces*, 72 Neb. L. Rev. 804, 806-07 (1993).

[6] *See Proceedings and Debates on the Securities Litigation Reform Act*, 104th Cong., 1st Session, 141 Cong. Rec. H2760-01 (daily ed. Mar. 7, 1995) (statement of Rep. Bliley) (citing survey of National Venture Capital Association finding "that 62 percent of responding entrepreneurial companies that went public in 1986 had been sued by 1993"). *See also* Jordan Eth & Michael Dicke, *Insider Stock Sales in Rule 10b-5 Corporate Disclosure Cases: Separating the Innocent from the Suspicious*, 1 Stan. J. of L., Bus. & Fin. 97, 98 n.5 (1995) (citing study showing that 38% of all shareholder securities suits are filed against companies traded on NASDAQ or over-the-counter markets, which have a high proportion of young growth companies).

[7] Randolph P. Beatty & Edward J. Zajac, *Managerial Incentives, Monitoring, and Risk Bearing: A Study of Executive Compensation, Ownership, and Board Structure in Initial Public Offerings*, 39 Admin. Sci. Q. 313, 324 (1994).

or who left the company and sold their stock. Because the decision where to set the bounds of the alleged class period is largely within the plaintiff's discretion, the odds can be improved even more by alleging a sufficiently long class period. Inasmuch as stock trades potentially serve as a ticket for avoiding dismissal or the entry of summary judgment, there is a strong incentive to define a class period that includes such trades.

Notwithstanding the frequency with which scienter allegations are based on stock sales, no clear analytical framework has been developed for addressing this issue. Indeed, in many cases, lower courts simply have treated allegations of stock sales during the class period as sufficient evidence *per se* of the requisite scienter.[8] Insofar as any standard has been articulated in these cases, the most frequently cited originally was set forth in *Goldman v. Belden*, 754 F.2d 1059, 1070 (2d Cir. 1985), which stated that stock sales "in suspicious amounts or at suspicious times" are probative of bad faith and scienter. Although other courts of appeals have repeated this formulation,[9] none of these subsequent decisions has found that a sale of a block of stock, even if *not* at a

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[8] *See, e.g., In re Exabyte*, 823 F. Supp. at 869 (plaintiffs have "alleged unusual levels of insider trading during the class period, which itself is sufficient to establish scienter"); *Searls v. Glasser*, [1992-1993 Tr. Binder] Fed. Sec. L. Rep. (CCH) ¶ 97,358, at 95,851 (N.D. Ill. Feb. 1, 1993) (sales of stock by insiders sufficient to infer bad faith); *In re 3Com Sec. Litig.*, [1990 Tr. Binder] Fed. Sec. L. Rep. (CCH) ¶ 95,270, at 96,247 (N.D. Cal. May 4, 1990) (allegation that insiders sold stock during class period sufficient to infer scienter); *Klein v. King*, [1989-1990 Tr. Binder] Fed. Sec. L. Rep. (CCH) ¶ 95,002, at 95,605 (N.D. Cal. Mar. 26, 1990) (allegation of "massive" stock sales during class period sufficient to support inference of fraud); *Lazar v. Gurevitch*, No. CV-90-6345, slip op. at 5-6 (C.D. Cal. Sept. 20, 1991) (contention that three defendants sold stock at a time when the price was inflated alone was sufficient to provide an inference of bad faith).

[9] *See, e.g., Greenstone v. Cambex Corp.*, 975 F.2d 22, 26 (1st Cir. 1992); *Rubenstein v. Collins*, 20 F.3d 160, 169 (5th Cir. 1994); *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1117 (9th Cir. 1989), *cert. denied*, 496 U.S. 943 (1990).

suspicious time, truly is so inherently "suspicious" that it alone suffices to raise an inference of securities fraud.

Indeed, in practice, courts of appeals since *Goldman* have emphasized that it is trading in a suspicious amount *and* at a suspicious time that gives rise to an inference of scienter. Illustrative is the Ninth Circuit's decision in *In re Apple Computer Securities Litigation*, 886 F.2d 1109 (9th Cir. 1989), *cert. denied*, 496 U.S. 943 (1990). In that case, the individual defendants sold approximately $84 million of Apple stock during the class period. The court nevertheless found that in that case, where the defendants' "overall pattern of conduct" was consistent with their claim to be acting in good faith, these stock sales were insufficient to give rise to an inference of scienter. 886 F.2d at 1118. In rejecting the plaintiffs' showing, the court observed that prior decisions had required sales dramatically out of line both in amount and timing to sustain an inference of bad faith:

> [T]hose cases basing a finding of bad faith on insider trades have involved trades in amounts dramatically out of line with prior trading practices at times calculated to maximize personal benefit from undisclosed inside information. *See, e.g., Lilly v. State Teachers Retirement System*, 608 F.2d 55, 56 (2d Cir. 1979), *cert. denied*, 446 U.S. 939, 100 S. Ct. 2159, 64 L.Ed.2d 792 (1980) (sale of 80,000 shares nine days prior to public announcement that "problem loans" had increased from $7 million to $16 million); *SEC v. Musella*, 578 F. Supp. 425, 441 (S.D.N.Y. 1984) (multiple episodes of stock trades within days or weeks of "public announcements having a significant market impact on the value of the securities"); *Jeffries & Co. v. Arkus-Duntov*, 357 F. Supp. 1206 (S.D.N.Y. 1973) (sale of 40,000 shares two days before the SEC suspended trading in the stock).

Id. at 1117-18; *see also Rubinstein*, 20 F.3d at 169-70 (inference of scienter satisfied at pleading stage where defendants sold significant amount of stock three weeks before announcement that dropped value of stock by one-third).

Most recently, in *Acito v. IMCERA Group, Inc.*, 47 F.3d 47 (2d Cir. 1995), the Second Circuit made it clear that despite the

language in *Goldman*, a trade involving a substantial block of stock alone is not enough to give rise to an inference of scienter. Indeed, the facts in *Acito* are closely on point to those at bar. In *Acito*, the complaint alleged that during the class period, IMCERA's CEO retired as an officer of the company (while remaining Chairman of the Board) and concurrently sold 60% of his holdings in IMCERA stock and options. Two months later, IMCERA received a deficiency notice from the FDA that, when disclosed, caused its stock to drop sharply. The Second Circuit found that these facts "did not give rise to a 'strong inference' of intent to deceive" sufficient to withstand a motion to dismiss. *Id.* at 54. Citing *Apple*, the court held that "while unusual insider trading activity during the class period may permit an[ ] inference of bad faith and scienter, plaintiffs have failed to establish that Kennedy's stock sales were 'unusual'." *Id.* The court noted that "the fact that the other defendants did not sell their shares during the relevant class period" further undermined plaintiffs' claim of scienter. *Id.*

The holding of the court of appeals in this case is squarely in conflict with *Acito*. Indeed, the Ninth Circuit found that Payne's sale of two-thirds of his stock when he resigned as CEO, more than a year before the negative disclosure, was sufficiently "suspicious" not merely to state a claim but to defeat summary judgment. The court reached the same conclusion with respect to Penfil, although he, like the CEO in *Acito*, sold his shares a full two months before receipt of the news that caused the stock to drop. As in *Acito*, no other Medstone officers or directors traded their shares during the class period; and, indeed, Medstone insiders were *purchasing* stock in the company right up to the eve of the bad news announcement. The principal difference in the cases highlights even further the conflict in their holdings. In this case, two years of exhaustive discovery confirmed that the defendants' overall course of conduct was consistent with their express statements of good faith. In *Acito*, by contrast, the allegations were found to be insufficient even to withstand a motion to dismiss.

Beyond this clear conflict with *Acito*, the Ninth Circuit's reasoning appears to go even further, in that the defendants' stock trades were found to support an inference of scienter regardless of

the lack of nexus, not only temporally but even *logically*, to the disclosed bad news. Thus, for example, the court attempted to link Penfil's trade in August 1989 to his purported inside knowledge of the results of the ongoing gallstone clinical trials, which the court stated were published in early September 1989. (A23). Yet the court did not require the plaintiff to show that the news of which Penfil was aware had any market significance. Nor could plaintiff have made such a showing: Medstone's stock price was virtually flat throughout August and September, when this information ostensibly was disclosed.[10] The same deficiency underlies the court's reasoning with respect to the defendants' trades a year earlier, in September 1988, when they purportedly had knowledge of the comparative results of the Dornier and Medstone machines. The fact which caused Medstone's stock to drop, however, was the FDA's decision not to accept its gallstone application, and the Ninth Circuit did not (and could not) link that decision to the relative merits of Medstone versus Dornier — the FDA rejected them both.[11]

Possibly even more troubling is the Ninth Circuit's further conclusion that stock sales are suspicious if they take place close in time to a public offering that is alleged to contain inadequate disclosures. This Court previously has recognized that Section 11 of the 1933 Act, which provides for a cause of action based on offering misstatements, "is subject to significant procedural restrictions not applicable under § 10(b)." *Ernst*, 425 U.S. at 209. It accordingly has rejected interpretations of Section 10(b) that

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[10] As it happens, there was good reason for this complete lack of reaction: the American Journal of Surgery articles to which the court adverts have a publication date of September 1989, but, as the papers state on their face, they were first presented — and hence publicly known — at a medical conference in *May* 1989. *See* David Vanderpool et al., *Biliary Lithotripsy*, 158 Am. J. Surgery 194, 194 (1989); Lawrence W. Way, *Trends in the Treatment of Gallstone Disease: Putting the Options Into Context*, 158 Am. J. Surgery 251, 251 (1989).

[11] See A3-A4. Ironically, when clinical results were published in July 1989 sufficient to undertake some meaningful comparison of the two trials, some in the investment community are noted in plaintiff's own Complaint as attributing the publication of these results to a jump up in Medstone's stock price. Class Action Complaint ¶ 84.

"would allow causes of action covered by § 11 . . . to be brought instead under § 10(b) and thereby nullify the effectiveness of the carefully drawn procedural restrictions on those express actions." *Id.* at 210.

The effect of the Ninth Circuit's rule, however, largely eviscerates the distinction between Section 11 and Section 10(b) for purposes of avoiding summary judgment. If, under the Ninth Circuit's reasoning, a defendant who trades three months after an offering should be suspected of attempting to profit from the omission, even greater suspicion should attach to sales in the offering itself: they involve the sale of large blocks of stock contemporaneously with the failure to make complete disclosure. Under the logic of the Ninth Circuit's reasoning, a plaintiff who could show under Section 11 that a triable issue exists because the registration statement contained a material misstatement, also would have raised a triable issue under Section 10(b) against the company and any officers who sold in the offering — and would have succeeded in circumventing the limitations of Section 11 in precisely the manner that the Court has proscribed.

In sum, this case and decisions such as *Acito, Apple*, and *Goldman* reveal an underlying confusion as to what standard should apply in determining whether executive stock sales are sufficient to raise an inference of scienter. This confusion has led to conflicting decisions in cases with virtually identical facts (like *Acito* and the decision below), and to an apparent collapsing of the different statutory provisions of the securities acts. Moreover, as discussed immediately below, there is yet another consequence of the rule adopted by the Ninth Circuit, namely, its probable perverse effect on the structure of executive compensation.

B. *The Ninth Circuit's Rule Has Serious Adverse Public Policy Consequences.*

In finding that the stock sales by Payne and Penfil gave rise to an inference of wrongful intent, the Ninth Circuit expressly rejected the view that departure from the company provided an alternative innocent explanation for the defendants' conduct. Rather, in the court's mind, this explanation left unanswered the question whether the defendants had acted "in order to reap large

returns," and did not dispel the suspicion that their sale aroused.[12] (A26). Under the court's rule, therefore, executives of public companies are on notice that if they take compensation in the form of options or stock, any attempt to dispose of a significant block of that stock may expose them to claims of securities fraud. Most strikingly, they will not even be able to liquidate their holdings when they change jobs, without exposing themselves to a securities fraud claim — and accordingly to potentially enormous financial exposure[13] — if anything goes wrong at the company long after they leave.[14]

This rule is likely to have a substantial chilling effect on the willingness of executives to take compensation in the form of stock, even though it is desirable from the point of view of the company's shareholders that they do so. In the last ten years,

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[12] The same position seemingly was taken by the Second Circuit in *Goldman* in the context of a motion to dismiss, in that the court treated as "suspicious" an executive's sale of his stock upon leaving the company. *Goldman*, 754 F.2d at 1070-71. While the viability of *Goldman* seems questionable in light of *Acito*, the Ninth Circuit's decision takes the analysis one step further in finding that such conduct is so unusual that it justifies not merely allowing discovery (as in *Goldman*) but compelling trial.

[13] In *Apple*, for example, after remand of the case from the Ninth Circuit, a jury verdict of approximately $100 million was imposed against two of the company's officers, *see* Richard B. Schmitt, *Apple Vice-Chairman, Ex-Officer Held Liable for $100 Million in Fraud Suit*, Wall St. J., May 31, 1991, at A3, before the verdict was set aside by the district court. *In re Apple Computer Sec. Litig.*, [1991 Tr. Binder] Fed. Sec. L. Rep. (CCH) ¶ 96,252 (N.D. Cal. Sept. 6, 1991) (granting officers' motion for judgment notwithstanding the verdict).

[14] The possibility of such an outcome poses a serious reputational as well as economic threat. The CEO of a major Silicon Valley company, for example, has testified that even though a suit against him and his company ultimately was dismissed, one of the most damaging consequences of the suit was that it put their integrity "into play." *Hearings on Private Litigation Under the Federal Securities Laws Before the Subcommittee on Securities of the Senate Comm. on Banking, Housing and Urban Affairs*, 103d Cong., 1st Sess. at 9 (1993) (statement of Edward R. McCracken).

economists and organizational researchers have recognized that there is a substantial potential conflict of interest, known as the "principal/agent" problem, between the executives and shareholders of a publicly held corporation. One example given in the literature is a CEO confronted with a decision whether to make a wasteful expenditure, such as purchasing new corporate jets, that benefits him personally but diminishes the market value of the company by, say, $10 million. For the median CEO of a large public company, "the stock-related 'feedback effect'" of this value-destroying investment is only about $6,600. Michael J. Jensen & Kevin J. Murphy, *CEO Incentives — It's Not How Much You Pay, But How*, 68 Harv. Bus. Rev. 138, 141 (1990).[15] By contrast, for a CEO who owns 45% of the company, "the stock-related feedback effect of a $10 million decline in market value is nearly $4.5 million — a much more powerful incentive to resist wasteful spending." *Id.*

The conclusion of such studies is that, to maximize corporate performance, senior executives should own a substantial amount of company stock. *Id.* This economic literature also recognizes, however, that such a compensation structure significantly enhances the financial risk that executives face. Unlike cash, which can be used to diversify a person's portfolio, compensation in the form of stock and options is highly exposed to firm-specific risks (for example, the vagaries of the stock market). Because of this greater riskiness, executives may prefer a weighing of compensation more heavily towards cash than stock.[16]

The Ninth Circuit's rule has the perverse effect of both substantially increasing the relative riskiness of incentive compensation, and simultaneously encouraging non-optimal behavior by

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[15] Taking into account all other aspects of compensation — for example, the likelihood of diminished bonus or of dismissal for poor performance — the same study estimated that the total lifetime change in expected wealth for the representative CEO would "decline by only $25,900 as a result of this misguided investment — not much of a disincentive for someone who earns on average $20,000 per week." Jensen & Murphy, *supra*, at 140.

[16] *See, e.g.*, Jensen & Murphy, *supra*, at 141-142; Beatty & Zajac, *supra*, at 316.

corporate managers. Thus, from the manager's perspective, the relative riskiness of stock and option compensation is substantially enhanced if such compensation is nondiversifiable not only during the manager's tenure at the firm, but even for a substantial period (possibly years) thereafter. From the point of view of the company's shareholders, moreover, there is no benefit to be derived from this increased risk. Indeed, from the shareholders' perspective, the optimal time for the liquidation of such compensation is after the executive's departure, when it no longer has the potential to affect company performance.

The Ninth Circuit's rule, however, systematically discriminates against that outcome. It leads to a stronger preference by executives for cash rather than incentive compensation, even though the interests of shareholders runs precisely to the contrary; and, if executives do receive incentive compensation, it encourages them to dispose of such shares regularly throughout their tenure, thereby minimizing the performance-enhancing effect of such compensation. It is ironic in this regard that the court of appeals in this case held up as a model, by comparison with the "suspicious" conduct of defendants Payne and Penfil, the practice of several Apple employees of regularly selling their Apple shares. (A26). It is not clear whom the court of appeals though would be benefitted by such conduct, but it was not the corporation's shareholders.

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The question of how much and under what circumstances company stock may be sold is of pressing importance to thousands of corporate managers, given the use of stock or stock options as a significant component of compensation at most publicly held corporations. The importance of this question is further underscored by the prevalence of shareholder class actions, which the American Business Conference described as "perhaps the No. 1 public policy issue" presently facing growth companies.[17] The economic risks associated with such litigation can hardly be overstated: in the San Francisco area alone, between 1988 and 1993, it is estimated that companies paid $500 million to settle

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[17] Bowers & Gupta, *supra,* at B1.

such lawsuits.[18] Given the uncertainty that presently exists on this issue, its importance in the determination of shareholder securities suits, and the question's broader consequences for corporate performance and executive compensation, the question is one that the Court should address.

II. The Question Whether There is a Duty to Disclose Preliminary Data Regarding Medical or Scientific Trials is One That This Court Should Address.

The issue of when and to what extent companies involved in the testing of new drugs or medical devices are compelled to disclose information prior to the completion of such tests is a question with broad public policy ramifications which this Court should resolve. To begin with, under the Ninth Circuit's test, pharmaceutical and medical device companies potentially are caught in a conflict between FDA practice and their securities disclosure obligations. More broadly, however, the information disclosed frequently is of compelling (or even life and death) interest far beyond those who are investors in the company. In opting for a rule of early disclosure, the Ninth Circuit has adopted a standard of materiality so low that it is likely to compel the disclosure of information that is itself affirmatively misleading. The potential mischief that would be caused by a premature announcement regarding the development of treatments for AIDS or cancer, for example, is readily apparent. The Court should take review to determine whether the Ninth Circuit's rule requiring premature disclosure of ongoing medical trials strikes the proper balance of competing societal interests.

A. *The Materiality Standard Adopted by the Court of Appeals is at Odds with at Least Three Other Circuits.*

In *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 406 (1976), this Court adopted a standard for materiality under Section 14(a) of the 1934 Act, which subsequently the Court extended to apply to claims under Section 10(b) of the Act. *See Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988). In *TSC*, the Court

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[18] Mark V. Boennighausen, *New Rules for a Nasty Game*, The Recorder, Nov. 9, 1993, at 1.

expressly rejected the standard that had been articulated by the court of appeals, namely, that materiality consisted of "all facts which a shareholder *might* consider important." 426 U.S. at 445 (quoting *Northway Inc. v. TSC Indus. Inc.*, 512 F.2d 324, 330 (7th Cir. 1975) (emphasis supplied by Court). The *TSC* Court reasoned that use of "might" was misleading because it was "suggestive of mere possibility, however unlikely." *Id.* at 449 (quoting *Gerstle v. Gamble-Skogmo, Inc.*, 478 F.2d 1281, 1302 (2d Cir. 1973)).

The court of appeals below cited both to *TSC* and to *Basic*, but then proceeded conspicuously to apply a "might" standard in determining the materiality of the omitted information under Section 11. The court employed this "might" standard both in determining whether statements in the prospectus were misleading, and in ascertaining whether the defendants had an affirmative duty to disclose the study results. On the first point, it concluded that there was a triable issue as to whether the two prospectus statements were misleading because investors "might" have hesitated to buy Medstone stock if they had known the omitted information. The court then reiterated: "Reasonable jurors certainly could differ on whether this information *might* affect the stock-purchasing decision." (A14) (emphasis added). In its separate analysis of the duty to disclose issue, the court again applied this standard, holding that "a reasonable jury could find that the study results *might* have given a reasonable investor pause." (A16) (emphasis added).

Although this Court has never addressed what standard for materiality should govern under Section 11, at least three other courts of appeals have expressly adopted the *TSC* standard for Section 11 cases.[19] In bringing itself into direct conflict with these circuits, the Ninth Circuit has fallen into precisely the trap

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[19] *See I. Meyer Pincus & Assocs. v. Oppenheimer & Co.*, 936 F.2d 759 F.2d (2d Cir. 1991); *Kronfeld v. Trans World Airlines, Inc.*, 832 F.2d 726, 731 (2d Cir. 1987), *cert. denied*, 485 U.S. 1007 (1988); *Isquith v. Middle South Utilities, Inc.*, 847 F.2d 186, 208 (5th Cir.), *cert. denied*, 488 U.S. 926 (1988); *Weilgos v. Commonwealth Edison Co.*, 892 F.2d 509, 517 (7th Cir. 1989). *See also In re Newbridge Networks Sec. Litig.*, 767 F. Supp. 275, 279 (D.D.C. 1991).

anticipated by the Court in *TSC*. Indeed, in choosing to apply this lower standard in compelling the disclosure of clinical information, the Ninth Circuit's rule will do worse than simply bury shareholders "in an avalanche of trivial information," as the Court feared in *TSC*. 426 U.S. at 449. Rather, as discussed in the next section, it could well lead to the disclosure of affirmatively misleading information to patients and their doctors on important health-related issues.

B. *The Ninth Circuit's Rule Is Likely to Compel the Disclosure of Misleading Preliminary Medical Data.*

The information which the court of appeals held the defendants may have been under a duty to disclose was data from a memorandum dated May 1988, summarizing certain initial observations for 27 patients at Baylor in what was ultimately a 600-patient clinical trial. The testimony of one of the Baylor physicians, unrebutted on the record, was that he viewed the results they were obtaining at that time as comparable to those reported for the Dornier machine the year before. Deposition of Dr. J. Patrick O'Leary at 194.[20] Nevertheless, the court concluded from its own review of the data that it showed a "much higher success rate for the German machine," and that such information might be of importance to a reasonable investor.[21] (A12). In reaching this conclusion, the Ninth Circuit's analysis

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[20] Presumably Dr. O'Leary was basing his opinion on a greater familiarity than that of the court of appeals not only with the machines, medical procedures, and patient observations involved, but also with the inherent variability and subjectivity of the ultrasound techniques used to measure the size of gallstone fragments.

[21] The Ninth Circuit found that this information was necessary to prevent two statements in the prospectus from being misleading. The first statement was that "the Medstone 1050 shockwave lithotripter system (the 'Medstone System' or 'System') has been used successfully to treat kidney stone patients since October 1986 and gallstone patients since January 1988." (Prospectus at 5). In its discussion of materiality, the Ninth Circuit failed adequately to explain how the simple statement that the system had been used to treat gallstones "successfully" since January 1988 (five months before the offering) could have been relied upon by a reasonable investor as a basis for making a purchasing

shows just how radical is the rule that it has adopted, both in terms of the uncertainty that it creates for medical device and pharmaceutical companies, and its potential for compelling the dissemination of misleading information about health issues to the public.

On the first point, two aspects of the court's analysis illustrate the predicament in which its ruling places companies in the medical device and pharmaceutical industries.[22] First, in looking at relative "success" rates, the court of appeals chose to compare the relative rates at which the two machines were breaking gallstones into fragments below a certain size. (A11-A12). Yet the only endpoint ever approved by the FDA was not "fragmenta-

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decision, when the prospectus simultaneously disclosed the fact that the machine was only operational at one facility at the time of the prospectus (*id.* at 5, 19); that the use of the machines with gallstones was still under investigation by the FDA (*id.*); that "the percentage of persons who have gallstones that will be susceptible to treatment by [gallstone] lithotripsy . . . is not presently known" (*id.* at 16); that only a "limited number" of patients had been treated to date (*id.* at 6); and that "no assurance can be given that the clinical trials for the use of the System in treating patients with gallstones under the [FDA permit] will be successful." (*Id.*)

The other statement that the Ninth Circuit found potentially misleading was that "the Company believes the Medstone System compares favorably with other lithotripters presently being offered by competitors with respect to the precision of its imaging system, its ease of patent handling, its simplicity of operation and design, its safety features and its success rate in treating patients." (*Id.* at 22). The Ninth Circuit did not find any aspect of this statement to be actionable with respect to a comparison of the Medstone and competing products in the treatment of kidney stones. Nor did it find the statement to raise any triable issue with respect to a comparison of the Medstone and other systems in the precision of its imaging system, its ease of patient handling, its simplicity of use and design, and its safety features. As for the "success rate in treating patients," the Ninth Circuit again did not adequately explain how an investor could have reasonably relied upon this statement with respect to the use of the machine in treating gallstones in view of all other disclosures contained in the prospectus.

[22] A recent study found that medical device companies are among the most frequent targets in shareholder class actions. *See* 139 Cong. Rec. S16,662 (daily ed. Nov. 20, 1993) (remarks of Sen. Domenici).

tion," but whether patients were "stone-free." As the FDA advised Medstone in writing in March 1989, "fragmentation of gallstones does not itself provide a clinical benefit," and accordingly "'stone-free status" should be the criterion for effectiveness." The Ninth Circuit does not explain how a company laboring under its holding would — or even could — go about determining what endpoints, other than the ones approved by the FDA, "might" be material and therefore must be disclosed. Indeed, it appears to place such companies in an entirely untenable position, where the securities laws compel the disclosure of information that the FDA may well prohibit, for the mirror image of the reason given by the Ninth Circuit — that the *disclosure* of such information would be potentially misleading.

Similarly, the preliminary data that the Ninth Circuit held Medstone might have had a duty to disclose was not statistically significant. What criterion, then, is Medstone, or any other company, to apply in determining when such a duty arises? Did it arise after the first 15 patients? 10? 5? And, although the objective of the clinical study was to determine stone-free rates after six months, the Ninth Circuit held that Medstone might have had a duty to disclose even though *no* patients had yet reached that benchmark. How is a company to go about determining which intermediate observation points "might" be considered material? The Ninth Circuit went so far as to consider the very first 24 hours out of the six-month period to be potentially material; a company following in the wake of its decision will have no choice but to conclude that *every* intermediate observation point gives rise to such a duty as well.

As great as is the confusion that is likely to be spawned by the Ninth Circuit's rule, the case illustrates perhaps even more clearly the spread of misinformation that well could follow in its wake. An estimated 20 million Americans have gallstones, and there are approximately 500,000 gallstone operations in this country a year, making it the most common form of surgery performed by a general surgeon. There is therefore naturally widespread public interest in the possibility of non-surgical alternatives for the treatment of gallstones. Against this backdrop, the Ninth Circuit would have had Medstone disclose, not merely to its investors but to the millions of Americans potentially affected by these medical

developments, that Medstone had a "success" rate within 24 hours of 18%, and Dornier of 80%. (A11, A12).

Because the Medstone machine already was approved for use with kidney stones, physicians reading such information could have made decisions about whether to utilize the machine as well on their gallstone patients based on this information.[23] The information on which they would have acted, however, would have been significantly misleading. First, it would have been misleading regarding the relative success rates of Medstone and Dornier. Nearly a full *year* after the May 1988 data that the Ninth Circuit focused on, enough patients had been evaluated over a sufficient period of time for the physicians involved in the study to publish their cumulative preliminary data. What this article, which was accepted for publication in a major medical journal, showed was that for the subset of patients common to both the German and American studies, the stone-free rates were comparable.[24] Patients in this subgroup treated with the Medstone machine were reported to be stone-free at rates of 25, 65 and 90 percent when measured after 1, 3, and 6 months, Burnett et al., *supra*, at 1011, patients in the same subgroup treated with the Dornier machine were stone-free at a rate of 45, 69, and

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[23] Once a drug or medical device is approved by the FDA for a specific disease, physicians may, in the exercise of their discretion, prescribe it for other conditions. This same possibility does not exist for drugs or devices that have not yet been approved by the FDA, because they are not available on the market. Even in such instances, however, the premature announcement of information about a purportedly promising drug for the treatment of life-threatening illnesses could well cause enormous frenzy and confusion.

[24] One of the factual errors underlying the Ninth Circuit's analysis was its assumption that the patient pools were the same. In fact, the German study excluded patients with more than three gallstones, while the American study did not. This difference had an enormous impact on the results reported in the studies, because such patients constituted a substantial portion of the population evaluated in the American study (approximately 44%), Sackman et al., *supra*, at 393, and both studies found that the greater the number of stones, the less likely it was that the patient would ultimately be stone-free. *See id.* 395-96; Burnett et al., *supra*, at 1011.

78 percent when at 2, 2-4, and 4-8 months. Sackmann et al., *supra*, at 395.

Even this information, however, plainly was preliminary, inasmuch as the same group of physicians reported four months later that their stone-free rate now was approximately 51% after 6 months. Burnett et al., *supra*, at 1015. This fluctuation serves to underscore how wildly misleading it is likely to be when companies like Medstone must disclose information that has the veneer of "the scientific evaluation of . . . harder data," (A15), but which in fact is based (as in this case) on no statistically significant information at all.

Perhaps even more importantly, two of the most significant questions being evaluated in the clinical studies were the characteristics of the patient population that could be successfully treated, and the side effects (if any) of the treatment. Yet the May 1988 data provided no adequate information on either of those subjects. An 18% "success" rate on 100% of those with gallstones might under some circumstances be more significant than an 80% success rate applied to a select group of 10% of that population. Without knowing what population figures are being used, the calculation of percentages can be deceptive and meaningless. The prospectus expressly advised that Medstone had no information on what the size of the treatable patient population would be, and that was one of the purposes of the clinical trial. The May 1988 Prospectus provides no information at all on that score. Under the Ninth Circuit's rule, however, a company in Medstone's position must now disclose that it has an 18% "success" rate, at a point when the obvious rejoinder is unanswerable: 18% of what?

The defendants strongly disagree with the Ninth Circuit that the two statements in the prospectus could have been relied upon by a reasonable investor in view of the disclosed facts that the trials had just begun, that only a "limited number" of patients had been treated, and that the crucial question of what patient population was responsive to the procedure was entirely unknown. (A14-A15). If such statements could have been materially misleading, however, the correct approach seemingly would be that the statements should not have been made at all — not that the company should have provided yet *more* misleading information.

This approach is the one rigorously followed by the FDA, which vigilantly monitors statements made by companies about their products before they have been approved. This case again provides an instance in point: nearly a year after the May 1988 data that the Ninth Circuit concluded should have been disclosed, the FDA sent Medstone a letter prohibiting it from holding a press conference with respect to the data disclosed in a medical conference that was available *as of April 1989*. Declaration of Richard Penfil ¶ 13.

Unlike the FDA, the Ninth Circuit has opted for exactly the opposite rule, creating an affirmative duty to disclose "scientific" information so broad that it appears unbounded even by such constraints as statistical significance. Because of the frequency with which shareholder class actions are brought in the Ninth Circuit — approximately 25% of such suits are filed in California alone[25] — its creation of this duty of disclosure has broad ramifications for the development of the law in this area. It also has potentially profound effects on pharmaceutical and medical device companies, by placing them in a position where the FDA prohibits them from saying something that the securities laws ostensibly require them to disclose. The question of the quality of information disclosed about developing medical technology is an important one that warrants the Court's attention.

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[25]Eth & Dicke, *supra*, at 99.

CONCLUSION

For all of these reasons, certiorari should be granted.

Respectfully submitted,

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May 10, 1995

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 92-55879, No. 92-56055

WILLIAM KAPLAN, Administrator of the Estate of Lois Kaplan, on behalf of himself and all others similarly situated; THOMAS DEVERE,

Plaintiffs-Appellants,

v.

FREEMAN ROSE; ERROL PAYNE; RICHARD PENFIL; DAVID RADLINSKI; WEEDEN & CO., L.P.; MEDSTONE INTERNATIONAL INC.,

Defendants-Appellees.

GEORGIANE KRAMER, on behalf of herself and all others similarly situated,

Plaintiffs-Appellants,

v.

FREEMAN ROSE; MEDSTONE INTERNATIONAL, INC.; ERROL PAYNE; DAVID RADLINSKI; WEEDEN & COMPANY,

Defendants-Appellees.

October 11, 1994, Filed

Appeals from the United States District Court for the Central District of California. D.C. No. CV-89-0740-AHS. D.C. No. CV-91-0308-AHS. Alicemarie H. Stotler, District Judge, Presiding.

Before: James R. Browning, Robert Boochever, and Andrew J. Kleinfeld, Circuit Judges.

BOOCHEVER, Circuit Judge:

William Kaplan appeals the district court's grant of summary judgment to the defendants in his class action alleging securities violations against Medstone International, Inc., various Medstone officers and directors, and an underwriter (hereinafter collectively referred to as "Medstone," or "the defendants," unless individual identification is required). Georgiane Kramer appeals the dismissal as res judicata of her similar class action against the same defendants.

Kaplan alleged that the defendants made numerous material false and misleading statements and omitted material information in the company's prospectus, in violation of § 11 of the Securities Act of 1933. He also alleged that the defendants made false and misleading statements, and omitted material information, from statements made after the prospectus on which the plaintiffs relied in purchasing shares of Medstone stock, in violation of § 10(b) of the Securities and Exchange Act of 1934. Medstone and Kaplan both moved for summary judgment. The district court granted Medstone's motions, finding that the prospectus statements were not false, that Kaplan had not shown reliance on the statements made after the prospectus, and that the defendants had not acted with scienter in making the post-prospectus statements.

On this appeal, the parties dispute which statements and omissions were properly before the district court on summary judgment. Kaplan also argues that there were material issues of fact whether the statements and omissions were false or misleading, whether the plaintiffs relied on the post-prospectus statements under the "fraud on the market" theory, and whether the defendants made the post-prospectus statements with scienter. The parties also dispute the secondary liability of Medstone's chief executive officer as a "controlling person." We reverse in part and affirm in part.

FACTS AND PROCEDURAL BACKGROUND

In 1984, Medstone International, Inc. began engineering, manufacturing, and marketing a shockwave lithotripsy system ("system") for the treatment of kidney stones. Lithotripsy treats kidney stones with soundwaves, disintegrating the stones without

invasive surgery. In January 1988, the Food and Drug Administration ("FDA") granted Medstone permission to begin clinical studies to test its system for the treatment of gallstones. Medstone began clinical evaluations. In April 1988, the FDA granted Medstone approval to sell its system to treat kidney stones.

In June 1988, Medstone issued its initial public offering. Medstone's prospectus stated that the Medstone system compared favorably with other lithotripters offered by competitors, that the system had been used successfully to treat kidney stone patients since 1986 and gallstone patients since January 1988, and that Medstone's marketing plan was based on its belief that 2,000 lithotripters would be installed in the United States in the next five to ten years to treat kidney stone and gallstone patients. Following the public offering, Medstone sold 1.15 million shares of its common stock at $13 per share.

In the year following the offering, Medstone issued a number of statements regarding the prospects of its gallstone lithotripsy system. For example, Medstone represented that its gallstone investigations were proceeding as expected; that the demand for lithotripsy to treat kidney stones and gallstones was on the rise and would result in increased demand for Medstone's system; and that Medstone's future was bright.

The price of Medstone's stock increased steadily following the June 1988 public offering to a high closing bid of almost $40 a share in August 1988. In the fall of 1988, Errol Payne resigned as Medstone's Chief Executive Officer ("CEO"), and shortly thereafter he and his family sold two-thirds of their stock, for $6.5 million. At about the same time, Richard Penfil, Medstone's President, and his family sold one-fourth of their Medstone stock for approximately $2.4-2.5 million. After Penfil's resignation in August of 1989, Penfil and his family sold the vast majority of their remaining stock for an additional $4.5 million.

By early October 1989, the Medstone stock price had decreased to $15 per share, and it continued to fall to $12 per share by October 18, 1989.

On October 20, 1989, the FDA announced that it would not approve Medstone's application for its system to treat gallstones, because it lacked "reasonable assurance that the device is effec-

tive." The FDA also denied the application for gallstone lithotripsy of Medstone's main competitor, the German company Dornier Medizintechnic GmbH ("Dornier"). A week following the October 20, 1989 announcement, the price of Medstone stock fell to as low as $6 per share.

On October 25, 1989, William Kaplan, as administrator of the estate of a Medstone shareholder, filed a shareholder class action against Medstone alleging violations of federal securities law. In addition to Medstone, Kaplan named the following defendants: Payne (Medstone's former CEO); Penfil (Medstone's former president); Freeman Rose (Medstone's Executive Vice President of Engineering at the time of the offering, and Medstone's CEO from July 1988 to July 1990); David Radlinski (Medstone's Vice President of Finance and Chief Financial Officer ("CFO")); and Weeden & Co. ("Weeden") (the underwriter of Medstone's initial public offering). Kaplan alleged that the defendants made false and misleading statements in the initial public offering on June 2, 1988, and that up until October 20, 1989, the date of the FDA's rejection of Medstone's application for approval of its gallstone lithotripsy system, they issued further misleading statements inflating the prospects for the success of Medstone's system in treating gallstones.

Shortly after Kaplan filed a second amended complaint on August 2, 1990, the district court granted Kaplan's motion for class certification. The deadline to amend the pleadings or join other parties was set at May 13, 1991.

On June 11, 1991, Georgiane Kramer, a member of the class of Medstone shareholders, filed a separate class action securities fraud complaint against the same defendants named in the Kaplan action. On October 7, 1991, the district court dismissed the Kramer complaint as barred by the statute of limitations, but later reinstated Kramer's claims regarding statements made after the prospectus. On March 17, 1992, Kramer filed a first amended complaint, and shortly thereafter filed a motion for consolidation with Kaplan.

Meanwhile, Kaplan filed a motion for summary judgment on his claims regarding statements in the prospectus and a motion for summary adjudication of facts on the claims regarding Med-

stone's statements after the prospectus. Medstone filed motions for summary judgment on all Kaplan's claims. The district court granted in full Medstone's motions for summary judgment and denied Kaplan's motions. Without ruling on Kramer's motion for consolidation, the district court dismissed Kramer as res judicata.

DISCUSSION

I. STATEMENTS BY MEDSTONE PROPERLY BEFORE THE DISTRICT COURT ON THE MOTIONS FOR SUMMARY JUDGMENT

A. The Nine Statements Before the Court on Summary Judgment.

We must first determine which of Medstone's statements are properly before us on appeal. Kaplan alleges that the district court improperly granted summary judgment for Medstone on thirteen statements that Kaplan claims were false and misleading. Medstone responds that only three of the alleged misstatements identified by Kaplan on appeal were before the district court on summary judgment, and that the remainder were specifically rejected as late attempts to amend the pleadings. Medstone is wrong. Nine of the thirteen statements challenged by Kaplan appear in Kaplan's second amended complaint. The remaining four appear in Kramer's original and amended complaints.

Of course, locating these statements somewhere in the pleadings does not answer whether they were properly before the district court on summary judgment, so that we may consider them on this appeal. To preserve his claims regarding these statements for appeal, Kaplan's opposition to Medstone's motions for summary judgment must have informed the district court of the legal or factual reasons why summary judgment was inappropriate. *Self Directed Placement Corp. v. Control Data Corp.*, 908 F.2d 462, 466-67 (9th Cir. 1990). *See also In re Worlds of Wonder Sec. Litig.*, 814 F. Supp. 850, 861 n.8 (N.D. Cal. 1993) ("*Worlds of Wonder I*") (where parties "have thrown in the proverbial kitchen sink" with numerous allegations of misleading statements or omissions in complaint, district court addresses only those contentions raised by parties in opposition papers), *aff'd in part*, No. 93-15321, slip op. at 11173 (9th Cir. Sept. 15, 1994).

All the alleged misstatements that Kaplan cites on appeal appear in the parties' motions for summary judgment. The district court expressly refused to consider the four statements which appeared only in the Kramer complaints, and we address them separately below. All but two of the remaining nine statements, contained in Kaplan's second amended complaint, either appeared in Kaplan's opposition papers to Medstone's motions for summary judgment or were addressed directly by the district court in granting summary judgment to Medstone. The two statements that were not quoted in Kaplan's opposition papers or in the district court's opinion appeared in Medstone's motion for summary judgment and were addressed generally in Kaplan's arguments regarding Medstone's future prospects and sales. On appeal, Kaplan argues that all these statements violated the securities laws. We therefore find none was abandoned on appeal. *Self Directed Placement*, 908 F.2d at 467.

We find that Kaplan included nine of the statements in his complaint, putting Medstone on notice as to those statements; adequately preserved his contentions regarding those nine statements at summary judgment; and properly presented his arguments regarding the statements in his brief on appeal. The first nine statements thus are properly before us.

B. The Four Additional Statements Rejected by the District Court.

Kaplan further argues that the district court erred in failing to consider four other statements which Kaplan alleged were false in his motion for summary judgment.[1] None of these statements

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[1] Those statements are as follows:

Statement 10. In April, 1988, the company won final [renal] approval by the FDA, clearing the way for the sale of 19 lithotripters . . . [in 1988]. (March 15, 1989 Los Angeles Times article)

Statement 11. Depending on the size and number of stones, fragmentation rates as high as 97 percent and stone-free results of 90 percent were achieved at six months following treatment. (April 25, 1989 Medstone press release)

Statement 12. Medstone sold its first PMA renal lithotripter after obtaining the PMA in the second quarter of 1988 and since then, such

appear in Kaplan's second amended complaint. Instead, two appear in the Kramer complaint, filed June 11, 1991, less than a month after the deadline to amend the pleadings in Kaplan. By the time the parties filed their motions for summary judgment, the Kramer complaint had been dismissed as barred by the statute of limitations.

The other two appear in the amended complaint in Kramer, filed March 17, 1992, after Kramer's § 10(b) claims were reinstated, more than four months after the parties submitted motions for summary judgment in Kaplan, and more than two months after argument on the summary judgment motions.

Thus at the time the summary judgment motions were filed, these four statements were not before the court in pleadings in either Kaplan or Kramer. The first two were in the initial Kramer complaint which already had been dismissed, and the last two, which appeared in the Kramer amended complaint, had yet to be alleged at all.

Nevertheless, Kaplan argues that the district court should have considered these four statements. First, he argues that the four statements were "fairly reflected" in his second amended complaint because they were connected to other statements alleged there. Second, he argues that the inclusion of these new statements constituted a motion to amend the complaint under Federal Rule of Civil Procedure 15, the denial of which was an abuse of discretion.

1. ***"Fairly reflected" in the complaint.***

Federal Rule of Civil Procedure 9(b) requires that "the circumstances constituting fraud . . . shall be stated with particularity." In a securities fraud action, a pleading is sufficient under Rule 9(b) if it identifies the circumstances of the alleged fraud so that the defendant can prepare an adequate answer. *Wool v. Tandem Computers Inc.*, 818 F.2d 1433, 1439 (9th Cir. 1987). The pleadings must state precisely the time, place, and nature of the misleading statements, misrepresentations, and specific acts of fraud. *Id.* at 1439-40. *See also Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989) ("the allegations should include the misrepresentations themselves with

particularity and, where possible, the roles of the individual defendants in the misrepresentations").

The four statements are missing entirely from Kaplan's second amended complaint and, at the time when the motions for summary judgment were filed, were not present in any pleading before the district court, except for Kaplan's summary judgment motion. We therefore conclude that the four statements are not fairly reflected in the complaint. The district court did not err in refusing to consider them. *Id.*

2. ***Motion to amend.***

An addition of new issues during the pendency of a summary judgment motion can be treated as a motion for leave to amend the complaint. *Roberts v. Arizona Bd. of Regents*, 661 F.2d 796, 798 n.1 (9th Cir. 1981). A district court's denial of leave to amend is reviewed for an abuse of discretion, keeping in mind the strong policy in favor of allowing amendment, and considering four factors: bad faith, undue delay, prejudice to the opposing party, and the futility of amendment. *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir. 1987).

The district court found that Medstone would suffer prejudice if Kaplan were allowed to amend the complaint, stating: "The parties have engaged in voluminous and protracted discovery . . . Expense, delay, and wear and tear on individuals and companies count toward prejudice." Trial was only two months away, and discovery was completed. *See Texaco, Inc. v. Ponsoldt*, 939 F.2d 794, 799 (9th Cir. 1991) (no amendment allowed where defendant "would have been unreasonably prejudiced by the addition of numerous claims so close to trial, regardless of [plaintiff's] argument that they were 'implicit' in the previously pleaded claims"). Further, Kaplan had already amended the complaint twice, and "a district court's discretion over amendments is especially broad 'where the court has already given a plaintiff one or more opportunities to amend his complaint'." *DCD Programs*, 833 F.2d at 186 n.3 (quoting *Mir v. Fosburg*, 646 F.2d 342, 347 (9th Cir. 1980)). Finally, two documents containing two of the statements were known to Kaplan from the beginning of the litigation, as evidenced by his complaint, which quotes from different portions of them both. Kaplan offers no evidence that he

was unaware of the sources of the other two statements. "Late amendments to assert new theories are not reviewed favorably when the facts and the theory have been known to the party seeking amendment since the inception of the cause of action." *Acri v. International Ass'n of Machinists*, 781 F.2d 1393, 1398 (9th Cir.), *cert. denied*, 479 U.S. 816, 93 L. Ed.2d 29, 107 S. Ct. 73 (1986). The district court did not abuse its discretion in refusing to consider the new allegations. We therefore hold that the district court properly excluded Statements 10-13.

II. KAPLAN'S § 11 CLAIMS

Kaplan alleges that Statements 1-3 in Medstone's registration statement were material, false, and misleading, and that the statements omitted material information about the success of and market for Medstone's system.

Under § 11 of the Securities Act of 1933, anyone who buys a security pursuant to a false and misleading registration statement may sue for damages. Section 11 states that any signer of the registration statement, any partner or director of the issuer, any professional involved in preparing or certifying the statement, and any underwriter of a registration statement may be liable "in case any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading . . ." 15 U.S.C. § 77k (1988).

The plaintiff in a § 11 claim must demonstrate (1) that the registration statement contained an omission or misrepresentation, and (2) that the omission or misrepresentation was material, that is, it would have misled a reasonable investor about the nature of his or her investment. *See In re VeriFone Sec. Litig.*, 11 F.3d 865, 868-69 (9th Cir. 1993). *See also In re Keegan Management Co. Sec. Litig.*, 794 F. Supp. 939, 944 (N.D. Cal. 1992) (misstatement is material if correct disclosure would have deterred, or tended to deter, the average prudent investor from buying the offered securities). *Cf.* 17 C.F.R. § 230.405 (information is material if reasonable investor would attach importance to it in considering whether to purchase securities).

No scienter is required for liability under § 11; defendants will be liable for innocent or negligent material misstatements or omissions. *Herman & MacLean v. Huddleston*, 459 U.S. 375, 382, 74 L. Ed. 2d 548, 103 S. Ct. 683 (1983). Defendants other than the issuer can establish a "due diligence" defense if they show that after reasonable investigation they had reasonable ground to believe (and did believe) that, at the time the registration statement became effective, the statements were true and there was no material omission. 15 U.S.C. § 77k(b)(3)(A).

Three of the nine misstatements alleged by Kaplan appear in Medstone's June 2, 1988, Registration Statement. The defendants potentially liable under § 11 are Medstone, as the issuer; Payne and Penfil, as directors and signatories; Radlinski, as a signatory; and Weeden, as the underwriter. The district court granted summary judgment in favor of the defendants on Statements 2 and 3 without mentioning Statement 1, although Statement 1 appears in Medstone's motion for summary judgment, Kaplan's opposition, and Medstone's reply, and Kaplan raises and discusses this statement on appeal. Statement 1 was fully briefed in the district court and is fully argued before us. Because we review a grant of summary judgment de novo, *Jones v. Union Pac. R.R. Co.*, 968 F.2d 937, 940 (9th Cir. 1992), we consider all three statements.

A. Misrepresentation.

Kaplan alleges that Statements 1-3 were false and misleading.

1. *Statement 1:* The Company believes the Medstone System compares favorably with other lithotripters presently being offered by competitors with respect to the precision of its imaging system . . . and its success rate in treating patients.

Kaplan argues that this statement was misleading because on June 2, 1988, the date of the offering, the clinical trials of Medstone's gallstone lithotripsy system could not be considered successful. Kaplan relies on a May 4, 1988 memorandum from Josh Burke, Medstone's Vice President of Regulatory Affairs, in which Burke presents a "brief, preliminary summary of data obtained from the first phase of the gallstone study at Baylor University." That memorandum states that five of 27 patients, or

18.5%, showed significant fragmentation of their gallstones (to fragments less than or equal to three millimeters) within 24 hours of treatment with the Medstone system. Those patients were classified as "successes."

Kaplan contends that this "dismal" success rate was misleadingly characterized as comparing favorably with Medstones' competitors' rates of success, and "could mislead potential investors by portraying that Medstone possessed a device that would be well received in the marketplace." Kaplan relies on a February 1988 New England Journal of Medicine article about a German test using a Dornier lithotripter on gallstone patients. Medstone submitted the article as an exhibit in support of its motions for summary judgment. The German study showed that 139 of 175 patients, or almost 80%, had no stones or had significant fragmentation (also to fragments less than or equal to three millimeters) within 24 hours of treatment. Kaplan argues that it was at least misleading to state that the Medstone system, with a 24-hour "success" rate of 18.5%, "compares favorably" to Dornier's system, with its 80% "success" rate.

Medstone responds by claiming that the German success rate cannot be compared to Medstone's, because the patients in the German study had undergone six months of lithotripsy. That is simply wrong. The German study reported that "one day after the first shock-wave treatment," of 175 patients two had no stones and 137 had small fragments (emphasis added). At between four and eight months, 63% of all patients in the German study had no stones at all. Contrary to Medstone's statement that "plaintiffs have submitted no evidence that Medstone's 18.5% success rate after just 24 hours of treatment compared poorly to the success rate achieved by the German studies for a comparable time period," there was material evidence to that effect in the article showing the German success rate of 80% after 24 hours.

We find there is a genuine issue of material fact whether Statement 1 was misleading.

2. *Statement 2:* The Medstone [lithotripsy system] has been used successfully to treat kidney stone patients since October 1986 and gallstone patients since January 1988.

Kaplan argues that because clinical trials of the Medstone system on gallstone patients had failed to achieve a significant or competitive level of success, it was false and misleading to state that the system had been "used successfully to treat . . . gallstone patients since January 1988," when the clinical trials began. As explained above, Medstone's system had achieved a success rate of 18.5% at the time of the prospectus statement, while the system of its competitor Dornier had a success rate of 80%.

Medstone replies that this statement was not literally false because one patient was stone-free in 36 hours, and 18.5% had significant fragmentation in 24 hours. The system was thus "used successfully" on this limited group of patients. Nevertheless, while it is literally true that some gallstone patients were treated successfully by the Medstone system, a material issue of fact remains whether Medstone misleadingly represented that the system was being used successfully on a regular basis, especially given the much higher success rate of the German machine. *See McMahan & Co. v. Wherehouse Entertainment, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990) (statement that is literally true may be considered material misrepresentation if misleading in context), *cert. denied*, 501 U.S. 1249, 115 L. Ed. 2d 1052, 111 S. Ct. 2887 (1991).

We find there is a genuine issue of material fact whether Statement 2 was false or misleading.

3. *Statement 3:* The Company's marketing plan is based upon its belief that within the next five to ten years there will be a total of approximately 2,000 lithotripters installed in the United States which will be used to treat kidney stone and gallstone patients.

Kaplan argues that this statement was misleading because it implies that Medstone would have a significant share of the lithotripter market. Kaplan also argues that Medstone knew the lithotripter market was saturated, relying on a September 1988 document in which Freeman Rose, then Medstone's CEO, wrote of the kidney machine market: "It's dead." Kaplan also points to Medstone's sluggish sales in 1988, and claims that Medstone knew it would not participate in any future market because of its system's low success rate with gallstone patients.

Medstone responds that there is no evidence that the market was saturated at the time the prospectus was circulated in June 1988. Medstone points to an independent study prepared as part of Weeden's two due diligence investigations, as the source of the projection of 2,000 installed lithotripters. Medstone also points out that Rose's "It's dead" statement was made three months after the date of the prospectus, and that the statement applied only to the market for single-purpose kidney lithotripsy systems. Rose testified at his deposition that the lack of demand for single-purpose machines gave Medstone's dual-purpose (kidney and gallstone) machine a competitive advantage. Finally, Medstone again asserts that the clinical trials were successful.

A statement in a prospectus will be grounds for liability under § 11 only if it was false or misleading at the time that the registration statement became effective. *See* 15 U.S.C. § 77k(a). Rose's "It's dead" statement was made three months after the prospectus was issued; it thus is not evidence to support a § 11 claim. *See Keegan Management*, 794 F. Supp. at 942 ("Because this information appeared so soon after the [public offering], it is tempting to assume, as Plaintiffs do, that Defendants must have had an inkling of it before the [public offering]. Yet the assumption may not be warranted; on summary judgment, Plaintiffs must produce evidence that it is."). Medstone also provided market figures to show that a substantial number of lithotripters were sold between 1988 and 1991, as evidence that the market was not actually saturated.

Finally, there is a basic flaw in Kaplan's argument. Statement 3 is not a prediction of Medstone's market but a general statement about the entire market for lithotripters. The success of Medstone's clinical trials thus has no direct relevance to this market estimate.

We conclude that there was no genuine issue of material fact regarding whether the market projection of 2,000 machines was false at the time that the registration statement became effective.

Summary judgment in favor of Medstone on Statement 3 was appropriate.[2]

B. *Materiality.*

Whether Statements 1 and 2 were material is also a question that should have been left for the jury. We find a rational jury could conclude that reasonable investors, reading these statements in the prospectus, could have been misled about the nature of an investment in Medstone. Such investors might have hesitated to buy Medstone stock if they had known that the success rate of Medstone's system, however preliminary, was far below that of its main competitor in the U.S. market. Reasonable jurors certainly could differ on whether this information might affect the stock-purchasing decision. *See Keegan Management*, 794 F. Supp. at 945.

Medstone argues that because its prospectus contained a cautionary statement, its optimistic assessment of the competitiveness and success rate of its system in Statements 1 and 2 is not misleading. In the "Risk Factors" section of the Prospectus, Medstone stated that "To date the System has only been used at one hospital on a limited number of patients. No assurance can be given that the clinical trials for the use of this System in treating patients with gallstones under the IND/IDE [the FDA approval to conduct clinical trials] will be successful." Medstone is not saved by pointing to this statement.

This court recently has adopted the "bespeaks caution" doctrine, which holds that if "'precise cautionary language . . . directly addresses itself to future projections, estimates, or forecasts in a prospectus,'" the projections will not give rise to a claim of securities fraud. *In re Worlds of Wonder Sec. Litig. (Worlds of Wonder II)*, No. 93-15321, slip op at 11173, 11186, 11188 (9th Cir. Sept. 15, 1994) (quoting *Worlds of Wonder I*, 814 F. Supp. at 858). *See Worlds of Wonder II*, slip op. at 11184-85 (citing cases from the First, Second, Fifth, Sixth, Seventh, and Eighth Circuits adopting the doctrine); *In re Convergent Technol-*

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[2] Because we conclude that there was no evidence that the market estimate was false at the time of the registration statements, we do not address whether Statement 3 was material.

ogies Sec. Litig., 948 F.2d 507, 515 (9th Cir. 1991) (applying a similar analysis without explicit reference to the doctrine). We need not apply the doctrine in this case, however, because the cautionary statement quoted by Medstone does not relate directly to Statements 1 and 2. While the statement that no assurance can be given that the clinical trials ultimately will be successful might "bespeak caution" as to the future success of clinical trials, *see Worlds of Wonder I*, 814 F. Supp. at 858-59, at least a jury question remains whether it neutralized Medstone's statement that its system already had been used successfully and was thus competitive.

We find that there is a genuine issue of fact whether Statements 1 and 2 were material.

C. **Omission of the Study Results.**

Kaplan also argues that Medstone had a duty to disclose the results of the Baylor clinical study in the prospectus, given the results detailed in Burke's memorandum. Medstone counters that the clinical data was too speculative and premature. If the failure to disclose the clinical results would have misled the reasonable investor about the nature of an investment in Medstone stock, then the omission was material. *VeriFone*, 11 F.3d at 868-69.

This is a close question. "Silence is not misleading in the absence of a duty to disclose." *In re VeriFone Sec. Litig.*, 784 F. Supp. 1471, 1480 (N.D. Cal. 1992), *aff'd*, 11 F.3d 865 (9th Cir. 1993). While internal forecasts need not be disclosed, *VeriFone*, 11 F.3d at 869, the scientific evaluation of clinical trials is harder data. Kaplan alleges the omission of "material, actual facts" from which forecasts of success may be derived. *Id.* Although a prospectus should not " 'bury the shareholders in an avalanche of trivial information'," *Basic Inc. v. Levinson*, 485 U.S. 224, 231, 99 L. Ed. 2d 194, 108 S. Ct. 978 (1988) (*quoting TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49, 48 L. Ed. 2d 757, 96 S. Ct. 2126 (1976)), this information was not trivial, as the efficacy and competitiveness of Medstone's system was essential to the company's performance.

Medstone argues that the study results were preliminary. But Medstone also bases its claim that Statements 1 and 2 were not

misleading on the same study, characterizing the results as successful. Having used the study results to justify its prospectus statements, Medstone may not simultaneously claim that the study was too preliminary to disclose.

Viewing the evidence in the light most favorable to Kaplan, we believe the inclusion of the test results might have explained what "successful" use of the Medstone system meant and whether it compared favorably with its competitors. The rate of fragmentation achieved by the Medstone system was well below the German machine's results, and is generally inconsistent with the term "successfully." We believe a reasonable jury could find that the study results might have given a reasonable investor pause. We therefore find there is a genuine issue of fact whether the omission of the study results was material, especially in the light of Medstone's statement that the lithotripter was competitive and had been used successfully.

D. **Weeden's Due Diligence Defense.**

Weeden moved for summary judgment on its defense of "due diligence" to the § 11 claims. To prevail on this defense at summary judgment, Weeden would have to show as a matter of law that, at the time of the registration statement, it had reasonable ground to believe and did believe, following a reasonable investigation, that the statements in the registration statement were true, that they omitted no required material fact, and that they contained all material facts necessary to ensure that statements in the registration statement were not misleading. 15 U.S.C. § 77k(b)(3)(A).

The district court noted that material issues of fact remained on the due diligence defense, although the court granted the defendants' motion for summary judgment on other grounds. Because the district court found that the prospectus statements were not false, it did not decide the motion for summary judgment on Weeden's due diligence defense. Because the defense was not decided below, and is not fully argued to us on appeal, we do not address it here.

Therefore, we reverse the district court's grant of summary judgment on the § 11 claims with respect to Statements 1 and 2;

we find that there are genuine issues of material fact as to whether these statements were material and misleading. In addition, we find that there is a genuine issue of fact whether the omission of the study results was material. However, we uphold the district court's determination that there is no genuine issue of material fact as to whether Statement 3 was false, and affirm the grant of summary judgment with respect to that statement. Finally, we decline to address Weeden's due diligence defense.

III. KAPLAN'S § 10(B) CLAIMS

Kaplan alleges that Medstone violated § 10(b) by making six post-prospectus statements, Statements 4-9, in Medstone's press releases, the Annual Report for 1988, and a research report prepared by Weeden. He also alleges that Statements 1-3 in the prospectus violated § 10(b).

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful to use any "manipulative or deceptive device" in connection with the purchase or sale of any security. 15 U.S.C. § 78j(b) (1988). Rule 10b-5, a regulation issued under § 10(b), makes it unlawful "to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of all the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b).

A projection or statement of belief is a "factual" misstatement actionable under § 10(b) if (1) the statement is not actually believed, (2) there is no reasonable basis for the belief, or (3) the speaker is aware of undisclosed facts tending seriously to undermine the statement's accuracy. *In re Wells Fargo Sec. Litig.*, 12 F.3d 922, 930 (9th Cir. 1993), *petition for cert. filed*, 62 U.S.L.W. 3863 (U.S. June 6, 1994) (No. 93-1993); *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989), *cert. denied*, 496 U.S. 943 (1990). A plaintiff under § 10(b) must show reliance on the material misstatement, and scienter (an intent to defraud or deceive). *See Hanon v. Dataproducts Corp.*, 976 F.2d 497, 506-07 (9th Cir. 1992).

In a securities fraud action, "materiality and scienter are both fact-specific issues which should ordinarily be left to the trier of

fact," although "summary judgment may be granted in appropriate cases." *Apple*, 886 F.2d at 1113. To survive summary judgment, a plaintiff in a securities fraud suit must show a genuine issue of material fact regarding a particular statement or statements by the defendant company or its insiders. *Id.* at 1118.

A. **Post-Prospectus Statements.**

Statements 4-9 contain optimistic pronouncements regarding Medstone's clinical trials for gallstone lithotripsy (4 and 8), the market demand for Medstone's machines (5, 6, and 9), Medstone's competitive position in the market (4), the volatility in its public stock prices (4), and its future success (6 and 7).

The individual statements are as follows:

Statement 4. There is no fundamental reason for the recent volatility in the company's common stock.... Our gallstone investigations are progressing as expected and our competitive position remains strong. (November 11, 1988 Medstone press release)

Statement 5. We believe noninvasive lithotripsy procedures for the treatment of kidney stones and gallstones will rise from 100,000 in 1987 to at least one million annually in the U.S. by the mid-1990s. This procedural demand should support an installed base, increasing from 200 machines at present, to in excess of 2,000 units in the U.S. alone. (November 15, 1988 Weeden Research Report)

Statement 6. Demand for Medstone lithotripters is strong and growing. (November 15, 1988 Weeden Research Report)

Statement 7. 1988 was an excellent year for Medstone.... We achieved exceptional financial results during the year and believe our outlook is bright. (1988 Medstone Annual Report)

Statement 8. The U.S. Food and Drug Administration (FDA) granted us permission in January 1988 to commence clinical trials to determine the safety and effectiveness of the Medstone STS for the treatment of gallstones. Progress is excellent. (1988 Medstone Annual Report)

Statement 9. The financial results for the first quarter were below plan, but we see increased sales activity compared to the

fourth quarter of 1988. The market is responding favorably to Medstone's Dual Imaging therapy system. (May 2, 1989, press release)

In granting Medstone's motion for summary judgment, the district court found that Kaplan failed as a matter of law to show reliance on any of the alleged misstatements because any material information Medstone had failed to disclose was made available to the market by other sources. The district court thus found that as a matter of law Medstone had not perpetrated a "fraud on the market." We therefore first discuss the reliance element of the § 10(b) analysis.

1. ***Reliance.***

Rather than alleging specifically the class's reliance on the statements in buying Medstone stock, Kaplan brought his claim under the "fraud on the market" theory, endorsed by the Supreme Court in *Basic*, 485 U.S. at 245-249, and described in detail in *Apple*, 886 F.2d at 1113-16. "Under the fraud on the market theory, the plaintiff has the benefit of a presumption that he has indirectly relied on the alleged misstatement, by relying on the integrity of the stock price established by the market." *Apple*, 886 F.2d at 1113-14. Kaplan's claim is that Medstone's alleged misstatements misled the market, the price of the stock responded accordingly, the plaintiff class bought the stock in reliance on the integrity of the price, and the class later lost money when the true state of affairs became clear and the price of Medstone's stock fell.

If, however, the information that defendants are alleged to have withheld from or misrepresented to the market has entered the market through other channels, the market will not have been misled, and the stock price will reflect the full universe of information, despite the defendants' misrepresentations. *Id.* at 1114. In such a case the element of reliance will not be satisfied, and plaintiffs' claims based on a fraud-on-the-market theory will fail. *Id.* at 1115 ("In a fraud on the market case, the defendant's failure to disclose material information may be excused where that information has been made credibly available to the market by other sources."). The information that the defendants withheld or misrepresented, however, "must be transmitted to the public

with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by the insiders' one-sided representations." *Id.* at 1116.

Because the fraud on the market theory affords § 10(b) plaintiffs a presumption of reliance, Medstone has the burden of producing evidence to rebut the presumption. *Basic*, 485 U.S. at 245; Fed. R. Evid. 301. To succeed at the summary judgment stage, Medstone's evidence must show that no rational jury could find for Kaplan on this issue. *Hanon*, 976 F.2d at 500. Our inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

Kaplan alleged that Medstone's optimistic statements 4-9 misled the market and omitted negative information about the success of the clinical trials, the likelihood of FDA approval, the size of the future market for lithotripsy and Medstone's place in the market, and the safety and efficacy of gallstone lithotripsy.

As evidence that the omitted information was conveyed to the market, Medstone submitted sixty articles discussing kidney and gallstone lithotripsy and published during the class period to the district court. Numbers can be deceiving. Only fourteen articles discuss Medstone specifically. An additional eight mention the company only in passing.

Six of the seven articles discussing Medstone's clinical trials are generally positive about the success of the trials, with a few cautionary notes. None predicts the low rate of success actually achieved by Medstone's system. Only one of the seven articles reports less than optimistic data. That single article is a summary of Medstone's clinical study results in the American Journal of Surgery, released one month before the end of the class period, which reported that only 10% of the patients who contacted the researchers ultimately were found eligible for lithotripsy, and that only 36% of those were stone-free after six months. The article concludes that surgical removal of the gall bladder is the "gold standard" of gallstone treatment, and lithotripsy "may or may not replace or sharply curtail surgery." Two articles discuss the much

more successful German trials of the Dornier lithotripter on gallstones.

The likelihood of FDA approval is addressed in eight articles, almost all of which assume approval is likely to be granted. Only two articles, from two stock analyst reports in September and October 1989, just before the end of the class period, express serious reservations. These articles warn that FDA approval may be "iffy,", and "there is a good chance . . . that Medstone will not receive panel approval." (emphasis in original).

General market estimates for lithotripters appear in ten articles, again mostly positive. Four articles forecast an eventual 2000 machines in the United States, one projects 400 by 1991, and two are generally optimistic. Only the remaining three, appearing in the two months before the end of the class period in October 1989, acknowledge that the market had leveled off and that Medstone's sales had dropped.

Over twenty general articles discussed the size of the gallstone patient group eligible for lithotripsy in sources including the New England Journal of Medicine (two articles), stock analyst reports, Associated Press and other newswires, the Los Angeles Times, Reader's Digest, medical specialty and business journals, the Denver Post, the Pittsburgh Post Gazette, and USA Today. These articles, however, gave widely varying estimates of the eligible patient group, ranging from 10%-80%, with most in the 20%-30% range.

A smaller group of fourteen articles mentions side effects. Of these, five said side effects were few, two had to do with kidney lithotripsy only, and four report possible kidney damage. Subsequent articles minimized the possibility of serious side effects.

Viewing this evidence in the light most favorable to Kaplan, we conclude that a genuine issue of fact remains whether, during the majority of the class period, cautionary information about the results of Medstone's clinical trials, the likelihood of FDA approval, the size of the lithotripsy market and Medstone's share in it, and the safety and efficacy of gallstone lithotripsy was "transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance" Medstone's allegedly misleading statements. *Apple*, 886 F.2d at 1116. The information

available during all but the very end of the class period was generally optimistic about the success of the clinical trials, the size of the market, the likelihood of FDA approval, and the prospects of gallstone lithotripsy in general and of Medstone in particular. In contrast to the evidence found sufficient for summary judgment in *Apple*, 886 F.2d at 1111-12, 1116, the negative articles Medstone submitted are not as numerous as the "at least" twenty articles from such sources as Business Week and the Wall Street Journal, citing the specific problems with a new computer. In fact, a significant number of the Medstone articles came from obscure sources, and only a few mention any specific problems. See *id.* at 1116 (not enough to refute fraud on the market theory where the omitted "information has received only brief mention in a few poorly-circulated or lightly-regarded publications").

We therefore hold that, for most of the class period, Medstone has failed to sustain its burden of establishing that no reasonable jury could find that the market was misled by its statements and omissions. "The total mix of information . . . sufficiently gives rise to different interpretations as to whether the representations and/or omissions made by [Medstone] were materially misleading to the market. The impression that this mix of information conveyed cannot be resolved as a matter of law." *Cooke v. Manufactured Homes, Inc.*, 998 F.2d 1256, 1262 (4th Cir. 1993) (citation omitted).

We emphasize that we do not hold that Kaplan has established his theory. We find only that Medstone has not eliminated the possibility that a rational jury could find that the alleged misrepresentations and omissions misled the market. Our role is not to weigh the conflicting inferences to be drawn from the articles presented by Medstone. That is a function that is properly left to the finder of fact.[3]

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[3] Medstone also argues that Kaplan's argument is contradictory, because the fraud on the market theory assumes an efficient market, and the only way to argue that the 60 articles did not reach the market is to concede that the market was not efficient. We reject this argument. As pointed out above, many of the 60 articles did not contain directly relevant information counterbalancing Medstone's public optimism. Some of the articles that did contain relevant information appeared in

The end of the class period presents a different picture. About two months before the October 20, 1989 FDA rejection of Medstone's application (which marks the end of the class period), detailed negative articles began to appear in such major sources as the Los Angeles Times Orange County Edition, the American Journal of Surgery, and two stock analyst reports. In combination, these articles fully apprised the market of Medstone's business problems and falling sales, the limited success of the clinical trials, the small eligible patient group, the possible side effects, and the possibility that FDA approval would not be forthcoming. Kaplan cannot claim that the market was misled after this information became available. We therefore agree with the district court that summary judgment was proper as to claims accruing after the beginning of September 1989, when Medstone's clinical results were published. All of the submitted articles after that time warned of the problems Medstone faced. The pessimistic conclusions in the study report, in conjunction with the Los Angeles Times article detailing Medstone's business problems and the later stock analyst reports predicting FDA rejection, were sufficient as a matter of law to counter the market effect of Medstone's earlier optimistic statements.

We therefore find that the district court erred in granting Medstone summary judgment on the fraud on the market theory only for claims accruing prior to September 1989. This factual issue is best left to the jury. *See Cooke*, 998 F.2d at 1262 (claims based on fraud on the market theory are fact-specific and generally for the trier of fact to decide). We affirm the district court's grant of summary judgment for claims accruing in the period beginning in September 1989.

2. ***Scienter.***

The district court also granted Medstone summary judgment on the scienter element of the § 10(b) claims, finding that Kaplan

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obscure sources. An efficient market will ignore irrelevant articles and articles that did not appear in sufficiently circulated and credible sources. The Supreme Court noted that the ultimate resolution of this question is an issue for trial. *Basic*, 485 U.S. at 249 n.29 ("proof [that information did not actually reach the market] is a matter for trial").

failed to produce evidence that the defendants intended to deceive investors.

In order to prevail on his § 10(b) claim, Kaplan must establish that the defendants made the allegedly misleading statements and omissions with scienter, "a mental state embracing intent to deceive, manipulate or defraud." *Hanon*, 976 F.2d at 507. Kaplan must show actual knowledge or a recklessness that is only one step down from intent, a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it. *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990) (*en banc*) (as amended), *cert. denied*, 449 U.S. 976 (1991) (citations and quotations omitted). Medstone moved for summary judgment on the issue of scienter, and submitted sworn declarations from each individual defendant, each testifying that he believed in good faith that his challenged statements (including Statements 4-9) were true. Medstone also submitted declarations regarding actions Medstone took in 1988 and 1989, including moving its operations to a larger facility, hiring more employees, increasing its inventory, and entering into an international distribution agreement in late 1988; an internal memo written in June 1989 regarding a productive meeting with the FDA; and positive statements made by FDA personnel in the spring and summer of 1989, as evidence that Medstone had a good faith belief in the future success of its system.

Kaplan's opposition repeated his allegations that Medstone had made false statements, using as specific examples three statements not even properly before the court on this appeal. Kaplan's opposition incorporates his own motion for summary adjudication on his § 10(b) claims, which asked for summary judgment on the issue of falsity only. He also referred the court to a declaration which was struck on a motion from Medstone.

Without the declaration, this portion of Kaplan's argument boils down to an assertion that "These statements are so false that defendants must have known they were false and must have intended to mislead the public." Such an argument does not suffice to rebut the declarations of good faith made by the

defendants. "A plaintiff . . . must offer more than conclusory allegations, and if the defendant presents affidavits or other evidence establishing a lack of scienter, the plaintiff must come forward with some affirmative showing." *Vucinich v. Paine, Webber, Jackson & Curtis, Inc.*, 739 F.2d 1434, 1436 (9th Cir. 1984) (*per curiam*). Kaplan, however, presented affirmative evidence as to several defendants.

a. *Insider trading.*

Kaplan presented evidence that Payne, Medstone's CEO at the time of the public offering, sold two-thirds of his stock in the fall of 1988 for $6.5 million, and Penfil, Medstone's president, sold one-fourth of his stock at the same time for $2.4-2.5 million. These sales occurred as soon as was legally possible after the public offering in June 1988. Penfil then sold the rest of his stock for another $4.5 million in August of 1989, just before the publication of Medstone's clinical results. Kaplan alleged that these sales coincided with the anticipation that negative information about Medstone would surface.

"Insider trading in suspicious amounts or at suspicious times is probative of bad faith and scienter." *Apple*, 886 F.2d at 1117. Payne and Penfil's stock sales, in conjunction with the allegations that they were aware of undisclosed negative information about Medstone, do raise suspicions about their intent, as they are massive sales at times alleged to have been calculated to avoid the negative effects of undisclosed inside information. *See Apple*, 886 F.2d at 1117 (cases basing scienter on insider trades "have involved trades in amounts dramatically out of line with prior trading practices at times calculated to maximize personal benefit from undisclosed inside information").

Medstone cites *Apple* to support its argument that Payne and Penfil's affidavits providing innocent explanations of their stock sales are sufficient as a matter of law to prove that no scienter existed. Payne explained that he sold the stock in the fall of 1988 after he decided to resign as CEO, to reap the economic rewards for the "significant effort and risk that I had invested in Medstone." Penfil explained that he and his family sold one-fourth of his stock in the fall of 1988 for the same reason as Penfil, and sold the remainder concurrent with his resignation in August of 1989

to ensure his financial security so he could spend more time with his family, and because he feared the possibility of hereditary early cancer.

In *Apple*, this court found that sales consistent with earlier patterns (and in much smaller amounts) did not create a genuine issue of fact regarding scienter in the face of "credible and wholly innocent explanations" for the sales. *Apple*, 886 F.2d at 1117. *Apple* does not apply here, however, for two reasons. First, these sales were not consistent with earlier patterns; they were in large amounts and at sensitive times. Second, Payne's and Penfil's explanations — that they wanted to reap financial benefits for personal reasons — merely beg the question of whether they acted on the basis of undisclosed inside information in order to reap large returns. Penfil's implication that he wanted to retire can even be read to support a finding of his scienter.

> [If defendant's] motivation in selling his stock was to fund retirement activities, plaintiff would doubtless argue that the desire to sell the stock to fund retirement was an incentive for [the defendant] to cause the making of inflationary misstatements. Such an implication would give substance to the contention that the alleged misrepresentations and omissions were deliberate.

Goldman v. Belden, 754 F.2d 1059, 1071 (2d Cir. 1985).

Viewing the evidence in the light most favorable to Kaplan, we find that the evidence of the stock sales was sufficient to create a genuine issue of material fact as to the scienter of Payne and Penfil, and through them Medstone.

b. *Good faith affidavits.*

Radlinski and Rose's affidavits present a different picture. Radlinski, Medstone's CFO, submitted affidavits stating that to the extent he made or participated in the statements alleged to be misleading in the prospectus and afterwards, he "acted in the good faith belief that each of the statements . . . [was] accurate and not misleading." He also stated that as to the statements made after the prospectus "I did not believe I was omitting any material information, and I was not aware of any objective fact

contradicting any of the statements." He also pointed out that he owned Medstone stock (he did not say how much) and had never sold any shares.

With his summary judgment motion, Rose (Medstone's CEO after Payne) submitted an affidavit stating that all the statements he made were true at the time and were made in good faith. He also stated that to his knowledge, all the information given to the public was true, and he never directed or induced anyone to make public statements that he knew were false or misleading. He stated that he owned approximately 101,000 shares of Medstone stock throughout the class period, and had never sold any.

Even viewing the evidence in the light most favorable to Kaplan, these affidavits, uncontradicted by any evidence of insider trading or other evidence of scienter, are enough to justify granting Radlinski and Rose summary judgment on the issue of their scienter. *See Worlds of Wonder II*, No. 93-15321, slip op. at 11210 (affirming summary judgment finding good faith where officers held on to stock during period of decline); *Apple*, 886 F.2d at 1117 (statements of good faith in affidavits were uncontroverted for purposes of summary judgment when there was no evidence of suspicious stock sales); *Bryson v. Royal Business Group*, 763 F.2d 491, 494 (1st Cir. 1985) (uncontradicted affidavit by CEO allows summary judgment on scienter).

c. *Weeden.*

Don Hill, the former Director of Corporate Finance of Weeden, also submitted an affidavit regarding Weeden's public statements following the offering. Hill's affidavit describes his reliance on the reports of the Wilkerson Group, a consulting firm, and his good faith in making any public statements about Medstone's market (including Statements 5 and 6, which appeared in a Weeden Research Report of November 15, 1988). He also purchased stock in Medstone just before the FDA denied approval in October 1989.

Hill is not named as an individual defendant, however, and his affidavit of personal good faith does not establish as a matter of law that Weeden lacked scienter. The district court cast some doubt on the reasonableness of Weeden's investigation and men-

tioned a possible conflict of interest in the context of Weeden's due diligence defense to the § 11 claims. Hill apparently became a member of Medstone's board right after the public offering. Unresolved issues remain regarding the objectivity of Weeden's investigation and Hill's membership on Medstone's board at a time when Weeden purported to perform objective research. Given the conflicting evidence, this affidavit from a single Weeden officer does not establish Weeden's lack of scienter as a matter of law for its statements after the initial public offering.

3. ***Falsity.***

Because it granted Medstone's summary judgment motion by finding as a matter of law that Medstone had rebutted Kaplan's presumption of reliance and that Kaplan had failed to establish scienter, the district court did not address the falsity of the post-prospectus statements made by Medstone after the initial public offering. The district court did address the falsity of the statements attributed to Rose, Statements 4, 8, and 9, and found they were not false.

We decline to address the falsity of any of the post-prospectus statements. Because we find that Kaplan produced no evidence that Rose or Radlinski had scienter, we find that summary judgment in their favor was appropriate on that ground. Further, as to the other defendants, Medstone's motion for summary judgment argued the issues of materiality and scienter, and the district court based its holding on those issues. On appeal, Medstone does not address the falsity of the post-prospectus statements, claiming that they are not properly before the court. We therefore do not decide the issue of the statements' falsity.

4. ***Materiality.***

In a § 10(b) action, an omitted fact is material if a reasonable investor would have been misled about the nature of an investment in Medstone, *VeriFone*, 11 F.3d at 869, because there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available." Basic, 485 U.S. at 231-32 (*quoting TSC Indus., Inc.* v. Northway, *Inc.*, 426 U.S. 438, 449, 48 L. Ed. 2d 757, 96 S. Ct. 2126 (1986)).

The parties' summary judgment papers and the district court's opinion, however, discuss materiality as if it were determined by whether the omitted information were credibly available to the market through other sources. Their discussion combines the fraud on the market theory of establishing reliance with the analysis of an individual statement's materiality. The two inquiries are closely related but not identical. A plaintiff who shows reliance under the theory that the market relied on a misrepresentation or omission must also establish materiality by showing that a reasonable shareholder would consider the misrepresentation or omission important, because it altered the total mix of available information.

The district court thus did not fully address the materiality of Statements 4-9. We therefore do not address it here. We note, however, that this issue is fact-specific and usually left to the fact-finder. *See Basic*, 485 U.S. at 239-41; *TSC Indus.*, 426 U.S. at 450 (materiality is mixed question of law and fact generally not properly resolved on summary judgment).

Therefore, as regards Kaplan's § 10(b) claims for Statements 4-9, we find that there is a material issue of fact as to reliance prior to September 1989. Moreover, there are material issues of fact regarding the scienter of Medstone, Payne, Penfil, and Weeden. Thus, we reverse the district court's grant of summary judgment for those defendants prior to September 1989. However, summary judgment was appropriate for any § 10(b) claims after that date. In addition, we affirm summary judgment for Rose and Radlinsky, as there is no genuine issue of material fact regarding their scienter.

B. The Prospectus Statements.

The district court granted summary judgment to Medstone on Kaplan's claim that Statements 1-3 in the prospectus violated § 10(b), finding that Kaplan had failed to show any evidence of scienter. Because we find that Kaplan presented a material question of fact regarding the scienter of Payne, Penfil, and Weeden, and because we find above that there is a material question of fact whether Statements 1 and 2 in the prospectus were false and material, we find that there is a material question

of fact whether Medstone, Payne, Penfil, and Weeden violated § 10(b) in making Statements 1 and 2 in the [4]

IV. ROSE AS A CONTROL PERSON OF MEDSTONE.

Kaplan does not argue on appeal that Freeman Rose is liable under § 11 for false or misleading statements made in the prospectus. (At the time of the offering, Rose was not a director of Medstone, and he did not sign the registration statement). We hold above that there was no material question of fact concerning Rose's lack of scienter in regard to statements made after the initial public offering, and so summary judgment on Rose's liability under § 10(b) for his own public statements was appropriate.

In addition to the summary judgment rulings on Kaplan's § 11 and § 10(b) claims, Kaplan also appeals the district court's holding that Rose was not secondarily liable for allegedly misleading statements made by the other defendants. Although Rose's position as CEO and his participation in the day-to-day affairs of the company were evidence that he exercised control over the other defendants, the court concluded that Rose was not a "controlling person" subject to liability for the statements of others because Kaplan "had not provided any evidence to support the contention that Rose was a culpable participant in the violations allegedly perpetrated by the other defendants."

Section 20(a) of the 1934 Securities Exchange Act provides:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t (a) (1988).

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[4] Because the district court did not consider the issue of reliance on Statements 1-3, we do not address it here.

Whether Rose is a controlling person "is an intensely factual question," involving scrutiny of the defendant's participation in the day-to-day affairs of the corporation and the defendant's power to control corporate actions. *Arthur Children's Trust v. Keim*, 994 F.2d 1390, 1396-97 (9th Cir. 1993). "A director is not automatically liable as a controlling person," although director status is a "red light" to the court. *Id.* (quotations omitted).

Rose was Medstone's CEO and a member of Medstone's board of directors during almost the entire class period. Kaplan also alleged Rose's significant participation in day-to-day activities at Medstone. Although Rose's status as an officer and director may not per se establish that he controlled the other defendants, his participation in the daily affairs of a relatively small company such as Medstone suffices to establish a material question of fact whether he was a controlling person. *See id.* Viewing the evidence in the light most favorable to Kaplan, we find that Kaplan alleged enough to survive summary judgment on Rose's status as a controlling person.

Rose relies on a line of cases holding that the plaintiff had the burden of showing that the defendant alleged to be a controlling person did not come within the good faith exception, thus requiring the plaintiff to show that the defendant had been a "culpable, knowing participant" in the misstatements. *See, e.g., Orloff v. Allman*, 819 F.2d 904, 906-07 (9th Cir. 1987). By a subsequent en banc decision, however, we have established that it is the alleged controlling person who has the burden of showing that he acted in good faith, and so did not share in the scienter required for liability under § 10(b). *Hollinger*, 914 F.2d at 1575. *See also Arthur*, 994 F.2d at 1398; *San Mateo County Transit Dist. v. Dearman, Fitzgerald and Roberts, Inc.*, 979 F.2d 1356, 1358 (9th Cir. 1992). Therefore, once Kaplan has shown a material question of fact whether Rose was a controlling person, the burden shifts to Rose to show as a matter of law that he acted in good faith.

Rose has met his burden. To establish his good faith, Rose submitted an affidavit in support of defendants' motion for summary judgment, stating that "during the time I was employed by Medstone, I never directed or induced anyone to make any public statements on behalf of or regarding Medstone which I knew to be false or misleading." Rose also stated: "To my knowledge, all

information released to the public was done entirely in good faith, was supported by fact, and was true." Kaplan points to no evidence disputing Rose's declaration of innocence.

Because an uncontradicted declaration of good faith can establish a lack of scienter, *see Apple*, 886 F.2d at 1117, Rose's uncontroverted statement that he never directed anyone to make statements that he knew to be misleading, and that to his knowledge all the information made public was true, is enough to shield him from secondary liability. Summary judgment was properly granted to Rose under § 20(a).

V. RES JUDICATA DISMISSAL OF KRAMER'S ACTION

Kramer argues that her complaint was improperly dismissed as res judicata, because the Kramer complaint contained allegations that did not appear in Kaplan. Those allegations were the allegedly misleading Statements 10-13, which Kaplan attempted to add to his complaint at the summary judgment phase. Kramer argues that the district court cannot find that the statements did not appear in Kaplan and yet dismiss them as res judicata in Kramer.

We need not address this argument. Because we reverse in part the grant of summary judgment to Medstone, the judgment that was the basis for res judicata is reversed. Kramer's § 10(b) claims will thus be reinstated, except to the extent we affirm the district court's grant of summary judgment in favor of Medstone as to all § 10(b) claims against Rose and Radlinski, and in favor of Rose on the claims based on secondary liability.

CONCLUSION

We find that Statements 1-9 were before the district court on summary judgment, and that the district court did not abuse its discretion in refusing to allow Kaplan to add Statements 10-13 at the summary judgment stage.

We reverse the district court's grant of summary judgment to Medstone, Payne, Penfil, Radlinski, and Weeden on the § 11 claims as to Statements 1 and 2, and on the omission of the study

results. We affirm the grant of summary judgment to the same defendants on Statement 3.

Further, we reverse the district court's grant of summary judgment to Medstone, Payne, Penfil, and Weeden on the § 10(b) claims with respect to Statements 4-9 and Statements 1 and 2 in the prospectus. Summary judgment was appropriate, however, for claims accruing after the beginning of September 1989. We affirm the grant of summary judgment to Rose and Radlinski, as there is no genuine issue of fact regarding their scienter.

We affirm summary judgment to Rose on the ground that Rose established a good faith defense to controlling person liability under § 20(a).

Finally, we reverse the district court's dismissal of the Kramer action as res judicata to the extent that we reverse the district court's grant of summary judgment to Medstone, Payne, Penfil, and Weeden on the § 10(b) claims.

Neither party is awarded fees or costs on appeal.

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

WILLIAM KAPLAN, ADMINISTRATOR OF THE ESTATE OF LOIS KAPLAN, on behalf of himself and all others similarly situated,

Plaintiff,

vs.

FREEMAN ROSE, ERROL PAYNE, RICHARD PENFIL, DAVID RADLINSKI, WEEDEN & CO., L.P. AND MEDSTONE INTERNATIONAL, INC.,

Defendants.

SA CV 89-740 AHS (RWRx)
consolidated with
SA CV 90-03 AHS (RWRx)

ORDER DENYING PLAINTIFFS' MOTION FOR SUMMARY ADJUDICATION AND SUMMARY JUDGMENT; GRANTING DEFENDANTS' MOTION TO STRIKE DECLARATIONS; DENYING PLAINTIFFS' MOTION TO STRIKE; GRANTING DEFENDANT ROSE'S MOTION FOR SUMMARY JUDGMENT; GRANTING THE MEDSTONE DEFENDANTS' PROSPECTUS AND POST-PROSPECTUS MOTIONS FOR SUMMARY JUDGMENT

I. BACKGROUND

Plaintiffs bring a class action on behalf of all persons who purchased or otherwise acquired the common stock of Medstone International, Inc. between June 2, 1988 and October 20, 1989 (the "class period"). Plaintiff William Kaplan is the administrator of the Estate of Lois Kaplan, a citizen of Pennsylvania who purchased 50 shares of Medstone common stock on July 25, 1988. Plaintiff Thomas DeVere is a self-proclaimed "resident" of New York who purchased a total of 7,000 shares of Medstone common stock on May 2, May 3 and June 15, 1989.

Medstone manufactures and markets a non-invasive shockwave therapy system which treats kidney stones, and, during the class period, was undergoing clinical tests pursuant to FDA preliminary approval of the system for gallstone therapy. Plaintiffs' claims stem from defendants' alleged failure to indicate accurately the progress of those clinical trials as well as the likelihood of final FDA approval of the machine's usage for gallstone therapy. Had defendants' "lithotripter" gained final FDA approval, Medstone would have dominated the lithotripsy market with the cheapest ($1.1 million, as opposed to their competitors' cost of $1.5-2 million) and only uniquely dual purpose renal (kidney stone) and biliary (gallstone) machine.

Plaintiffs purchased their stock when defendants had issued a series of allegedly false favorable public statements which drove the stock price up to approximately $45 per share. Upon the public announcement of the FDA's decision not to grant final approval of Medstone's machine for gallstone treatment on October 20, 1989, however, the stock price plummeted to approximately $3 per share.

Plaintiffs filed a motion for summary adjudication with regard to the Section 10(b) claims and a motion for summary judgment with regard to the Section 11 claims on November 13, 1991. On that same date, defendant Freeman Rose filed a motion for summary judgment and all defendants filed dual motions for summary judgment, one as to statements in the prospectus and another as to post-prospectus statements. All parties filed opposition December 10, 1991, except for plaintiffs with regard to defendant Rose's motion, who filed opposition to that motion December 11, 1991. Replies were filed as to all motions on December 23, 1991.

Plaintiffs filed a Motion to Strike Declarations in Support of Defendants' Motions for Summary Judgment on December 10, 1991. Defendants filed opposition December 23, 1991. Defendants filed a Motion to Strike Declarations of Douglas Campion, Tracy Thrower and John Torkelson Submitted by Plaintiffs in Opposition to Defendants' Motions for Summary Judgment on December 16, 1991. Plaintiffs filed opposition December 23, 1991. Defendants filed their reply December 30, 1991.

The matters were set for hearing on the Court's January 6, 1992 calendar. The Court heard the parties' arguments and took the matters under submission. By this Order, the Court denies plaintiffs' motions, grants defendant Freeman Rose's motion, grants defendants' prospectus and post-prospectus motions, grants defendants' motion to strike, and denies in its entirety plaintiffs' motion to strike.

II. DISCUSSION

A. The Summary Judgment Standard

In order for a plaintiff to succeed on a motion for summary judgment, it must show affirmatively through admissible evidence that there is no genuine issue of material fact as to each element of its claim and merely point out defendants' lack of evidence to support its affirmative defenses. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). To defeat a plaintiff's motion, a defendant must set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e).

In order for a defendant to succeed on a motion for summary judgment, it must demonstrate that there is no genuine issue of material fact by pointing out the absence of evidence produced by the plaintiff to support his case. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). In the alternative, a defendant may demonstrate affirmatively through admissible evidence that there is no triable issue of material fact as to each element of its affirmative defenses and that it is therefore entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). *See also, Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986).

"A complete failure of proof concerning an essential element of the nonmoving party's case renders all other facts immaterial." *Celotex Corp. v. Catrett*, 477 U.S. at 323. Where the material facts are under the moving party's control, the party's failure to produce such evidence may either preclude summary judgment or allow further discovery. *See Fontenot*, 780 F.2d at 1195.

On the other hand, in order to overcome a defendant's summary judgment motion, a plaintiff must set forth specific facts indicating that there is a genuine issue for trial, i.e., he must present evidence sufficient for a jury reasonably to find for him

instead of for defendant. Fed. R. Civ. P. 56(e). *See also, Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986). Particularly, in securities cases under Section 10(b), a "plaintiff[ ] may defeat summary judgment only by showing a genuine issue of material fact with regard to a particular statement by the defendant corporation or its insiders." *In re Apple Computer Securities Litigation,* 886 F.2d 1109, 1118 (9th Cir. 1989), *cert. denied*, 110 S.Ct. 3229 (1990). The Court is not to determine issues of credibility on a motion for summary judgment; instead, the truth of each party's affidavits must be assumed. *T.W. Elec. Serv. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

B. Section 10(b) and Section 11 Standards

1. ***Section 10(b)***

Rule 10b-5, enacted under Section 10(b), makes it unlawful "[t]o make any untrue statement of fact or to omit to state a material fact necessary to make the statements made, in light of all the circumstances in which they were made, not misleading." To state a claim under this section, plaintiffs must allege (1) material misstatements or omissions, (2) with an intent to deceive or defraud ("scienter"), (3) made in connection with the sale or purchase of any security (4) made through the use of instrumentalities of interstate commerce on the national securities exchange as well as (5) plaintiffs' detrimental reliance on these misstatements and omissions. *See, e.g., In re 3Com Securities Litigation*, [1990 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 95,270 (N.D. Cal. 1990).

Projections and general expressions of optimism may be actionable under Section 10(b). *See Marx v. Computer Sciences Corp.*, 507 F.2d 485, 489-92 (9th Cir. 1974). A projection or statement of belief is actionable to the extent it contains an inaccuracy or falsity with regard to one of the following implied factual assertions: (1) that the statement is genuinely believed; (2) that there is a reasonable basis for such a belief; or (3) that the speaker is unaware of any adverse undisclosed facts which would tend to undermine the accuracy of the statement at issue. *See In re Apple Computer Securities Litigation*, 886 F.2d 1109, 1113 (9th Cir. 1989), citing *Marx*, 507 F.2d at 490.

2. *Section 11*

Section 11(a) encompasses untrue statements of material fact and omissions of material fact in registration statements and reaches a broad group of defendants: (1) every person who signed the registration statement; (2) every director or partner of the issuer as of the time of the registration statement's filing; (3) every person named, with his or her consent, in the registration statement as one about to become a director; (4) every accountant, engineer, appraiser or similar professional involved in preparing or certifying any portion of the registration statement; and (5) every underwriter of the security. 15 U.S.C. § 77k(a).

To prevail on a Section 11 claim, plaintiffs must establish three elements: (1) standing, (2) the existence of a false or misleading statement in the applicable registration statement, which was false or misleading as of the effective date of the registration statement and (3) materiality. 15 U.S.C. § 77k. Proof of reliance is required by a purchaser who acquires securities after the issuance of an earnings statement covering a period of twelve months commencing after the effective date of the registration statement. 15 U.S.C. § 77k(a). (In the instant case, Medstone issued such a statement on August 3, 1989; therefore, any members of the class who purchased after this date to the end date of the class period, October 20, 1989, must prove reliance.)

Only purchasers of "'stock actually issued in the offering for which the plaintiff[s] claim[] there was a false or otherwise misleading registration statement'" may bring an action under Section 11. *Guenther v. Cooper Life Sciences, Inc.*, 759 F. Supp. 1437, 1439 (N.D. Cal. 1990) (quoting *Abbey v. Computer Memories, Inc.*, 634 F. Supp. 870, 872 (N.D. Cal. 1986). In order to establish standing, plaintiffs must demonstrate that they either (1) purchased shares directly in the public offering for which the misleading registration statement was filed or (2) purchased shares which are traceable to that offering. *Id.* Plaintiffs have the burden of tracing their shares. *Id.*

a. *Section 11 "Materiality"*

Plaintiffs and defendants disagree as to which standard of "materiality" applies to Section 11 claims. Plaintiffs contend that

the standard enunciated under 17 C.F.R. § 230.405 applies: "[t]he term *material*, when used to qualify a requirement for the furnishing of information as to any subject, limits the information required to those matters to which there is a substantial likelihood that a reasonable investor would attach importance in determining whether to purchase the security registered." Defendants argue that the materiality standard announced by the Supreme Court in *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976) applies: "[]an omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote . . . Put another way, there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable shareholder as having significantly altered the 'total mix' of information made available."

Plaintiffs' standard appears to be the applicable one. Defendants' urged standard was announced in the context of a 1934 Act claim, not a Section 11 claim under the 1933 Act as plaintiffs brought here. Accordingly, the materiality standard put forth by defendants is applicable to plaintiffs' Section 10(b) claim and plaintiffs' stated materiality standard controls their Section 11 claim.

b. *The "Due Diligence" Defense*

"Due diligence" constitutes an affirmative defense to a Section 11 claim, available to all except the issuer, on which the defendant has the burden of proof. 15 U.S.C. § 77k(b)(3)(A). Section 11(b)(3) provides that a defendant will succeed on a due diligence defense where he provides sufficient evidence that "[h]e had, after reasonable investigation, reasonable ground to believe and did believe, at the time such part of the registration statement became effective, that the statements therein were true and that there was no omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading." *Id.* Or, in other words, a defendant must establish that he made a reasonable investigation and actually held a reasonable belief as to the veracity of the registration statement. A "reasonable" investigation is one which a prudent man in the

management of his own property would conduct. 15 U.S.C. § 77k(c).

C. Plaintiffs' Section 10(b) Motion

1. *Defendants Argue that the Statements Moved on by Plaintiffs are not Specifically Enumerated in the Complaint*

Defendants argue that since the eleven statements and three omissions on which plaintiffs base their Section 10(b) motion are not specifically enumerated in their Second Amended Class Action Complaint (hereafter complaint), which has been the subject of at least two rounds of amendment, no judgment can be entered in plaintiffs' favor with regard to them. Defendants contend that plaintiffs' "eleventh hour" attempt to accomplish a *de facto* amendment to the complaint via summary judgment prejudices them since (1) they had no prior notice that plaintiffs would base their claims in part on these unpleaded statements; and (2) the new statements are alleged to be false *per se*, whereas those in the complaint are only alleged to be misleading due to the omission of assertedly material information.

Moreover, plaintiffs' failure to specifically enumerate these statements in their complaint flies in the face of the requirement that fraud be pled with particularity, defendants urge. *See Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). Finally, defendants argue that the Court should not allow plaintiffs to amend their complaint since to do so would severely prejudice defendants, in light of the filing of these voluminous summary judgment motions and the upcoming trial. (At the time of oral argument, trial was scheduled for February 18, 1992, with a 20-day estimate.) For this contention, defendants principally rely on *Roberts v. Arizona Board of Regents*, 661 F.2d 796 (9th Cir. 1981) and *Acri v. International Ass'n of Machinists*, 781 F.2d 1393 (9th Cir. 1986).

In reply, plaintiffs argue that: (1) by way of the specifically pleaded allegations of false statements in the complaint, defendants were put on notice of the particular statements for which plaintiffs now seek summary adjudication; and, (2) even if the Court finds that the misstatements moved on are somehow not contemplated by the allegations in the complaint as they now

stand, an amendment to the complaint should be allowed under Fed. R. Civ. P. 15(b) since "the presentation of the merits of this action will be subserved thereby and the objecting party fails to satisfy the [standard] that the admission of such evidence would prejudice the [objecting] party . . . ."

Plaintiffs point to Paragraph 36 in the complaint to bolster their argument that the complaint encompasses additional statements along the lines of those already specified within it. Paragraph 36 states in relevant part: "[t]hroughout the Class Period, defendants disseminated to plaintiffs and members of the class, the investing public and the financial community a series of false and misleading statements, including *inter alia*, those particularized in §§ 38-71 . . . ." Moreover, plaintiffs point to Paragraphs 2, 27 and 36 in the complaint to refute defendants' argument that the complaint alleges only statements rendered misleading due to omissions rather than those which are misleading purely because they are allegedly false *per se*.

Thus, plaintiffs' primary contention is that the "pleading fraud with particularity" requirement under Fed. R. Civ. P. 9(b) requires that only a few statements which typify the universe of fraudulent statements on which the entire action is based be specified in the complaint. On the other hand, defendants contend that each purportedly fraudulent statement must be specifically alleged in order for a defendant to have adequate notice of the full extent of the claimed fraud.

The prevailing standard in this circuit is that articulated in *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). Under *Moore*, "mere conclusory allegations of fraud are insufficient" but "statements of the time, place and nature of the alleged fraudulent activities" are sufficient to plead fraud. *Id.* Allegations based on information and belief have been deemed sufficiently "particular" in the context of corporate fraud, so long as the facts on which the belief is based are included, and the allegations include the *misrepresentations themselves with particularity* and the roles of the individual defendants in the misrepresentations. *Id.* The touchstone of analysis is whether the complaint sufficiently identifies the allegations constituting fraud "so that a defendant may prepare an adequate answer" therefrom. *Id.* What constitutes an "adequate answer" was stated in

Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir. 1985): "Rule 9(b) ensures that allegations of fraud are specific enough to give defendants notice of the *particular misconduct* which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." [citations omitted; emphasis added.] The *Semegen* court noted the salutary effect of Rule 9(b): "It also prevents the filing of a complaint as a pretext for the discovery of unknown wrongs and protects potential defendants . . . from the harm that comes from being charged with the commission of fraudulent acts." *Id.* The time, place and manner of the fraudulent statements at issue here are not alleged in the complaint. The complaint's allegations coming closest to the statements put in issue by plaintiffs' motion are these: during the class period of June 2, 1988 to October 20, 1989, defendants disseminated "a series of false and misleading statements . . . concerning Medstone's management, products, market business, financial condition, earnings and present and future business prospects" in "public statements and reports, including financial statements and other reports, releases and statements." *See* ¶¶ 36, 74 of complaint. Specific allegations in paragraph 74(a) - (x) indicate the financial reports and some of the press releases which contain the allegedly fraudulent statements.

After their motions to dismiss were denied because the Court deemed these allegations adequate enough to call for an answer, defendants did file their answer essentially denying what appeared in the complaint. But, plaintiffs rely on none of these in their motion for summary adjudication. Instead, plaintiffs allege eleven new charges of falsity and three new omissions and ask the Court to find that defendants can raise no triable issue as to any of them. Defendants understandably object to de facto amendments by plaintiffs at this late date, allege that they have been prejudiced, and urge that plaintiffs be precluded from basing a Rule 56(d) motion on unpleaded allegations.

The Court agrees with defendants. The parties have engaged in voluminous and protracted discovery shown in part by the enormous quantity of material submitted for these motions. Defendants should not fail on a motion for summary adjudication because they could not anticipate what plaintiffs would cite as

fraudulent conduct over two years after the action was begun. And, although defendants have managed to refute many of plaintiffs' new allegations, this does not mean that defendants have not been prejudiced. Expense, delay, and wear and tear on individuals and companies count toward prejudice. For these same reasons, plaintiffs will not be heard to amend their complaint with new grievances at this stage. Since the Court finds persuasive the defendants' position that the statements on which plaintiffs base their summary judgment motions are not a part of the complaint which defendants answered, the Court does not need to reach the merits of plaintiffs' motion.[1] Accordingly, plaintiffs' motion for summary adjudication as to their Section 10(b) claim is denied.

D. Plaintiffs' Section 11 Motion

1. *Defendants' Contention that the Motion Cannot be Granted Because it is Based on Unalleged Misstatements*

Defendants also contend with regard to this motion that plaintiffs base it on unalleged misstatements. In response, plaintiffs point to Paragraph 85 of the complaint, which states that the Section 11 claim is based on, inter alia, defendants' failure "to disclose material adverse information about the businesses, operations, financial condition and future business prospects of Medstone, including [those] stated in [paragraphs] 74(a) - (x) above" as well as defendants' alleged omission of material facts from the registration statement. In this context, where defendants have a concrete referent (the registration statement) from which to gauge plaintiffs' allegations, the Court finds defendants' argument unpersuasive. Under the *Moore* standard, 885 F.2d at 540, these allegations do encompass the statements on which plaintiffs base their motion.

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[1]Because the parties and now the Court have expended considerable time and effort in dissecting these uncharged allegations and their falsity, lack thereof, or misleading nature, in the interest of expediency the Court discusses the allegations on the merits in Appendix A to this order.

2. ***Defendants' Contention that Plaintiffs have Failed to Establish Standing to Sue under Section 11***

Defendants contend that plaintiffs have failed to provide any evidence that class representative Devere and others similarly situated to him purchased shares offered in the June 2, 1988 public offering or that their shares can be traced to that offering. In their reply, plaintiffs indicate that they do not move for summary adjudication here on behalf of Devere and others like him. Accordingly, Devere's standing is not an issue and the Court therefore makes no ruling with regard to it.

3. ***The Alleged Misstatements in the June 2, 1988 Registration Statement***

a. *"The Medstone 1050 ST shockwave lithotripter system (the "Medstone system" or "system") has been used successfully to treat kidney stone patients since October 1986 and gallstone patients since January 1988."*

Plaintiffs contend that this is a misstatement to the extent it characterizes gallstone treatments as being "successful," in light of the preliminary results of the first clinical trials at Baylor University outlined in a May 1988 memorandum from Medstone employee Burke to defendant Penfil. (Ex 37). Plaintiffs contend that only disclosure of the actual clinical data, which indicates the small sampling from which the statistics were taken and the prescreening of candidates, could save this statement from being misleading.

Moreover, plaintiffs contend that the stone fragmentation experienced by the patients did not constitute successful treatment. In order to compete with the surgical alternative, they urge that the only measure of success would be a completely stone-free bladder. They also present the expert testimony of Dr. Way and Dr. Greenberger, in which Dr. Way indicates that preliminary results were not promising and Dr. Greenberger states that the universe of eligible patients for the gallstone lithotripsy procedure is rather small. (Way Tr. at 118; Greenberger Tr. at 68). In their reply, plaintiffs add that defendants were under a duty to disclose the clinical results once they described them as being successful, citing *Virginia Bankshares v. Benson*, 559 F.2d 1307, 1317 (5th Cir. 1977), *cert. denied*, 435 U.S. 952 (1978).

Defendants contend that plaintiffs have failed to carry their burden of producing evidence which would indicate that Medstone's system was not used successfully on gallstone patients between January and June 1988. They argue that since Medstone was at an early stage of product development, it had no duty to disclose the particulars of these preliminary results. *See Convergent*, 948 F.2d at 516 (in the context of section 10(b) and under the circumstances presented, no duty to continually disclose progress of a company's efforts to the public existed). Moreover, they point out that later in the registration statement, there is an indication that the determination of "success" was based on preliminary clinical trials alone. (Plaintiffs' Ex 124 at 6). Finally, they contend that the experts' depositions do not directly contradict this registration statement, as they merely reflect two opinions in hindsight on the preliminary trial results (which are not indicative of the statement's truthfulness in light of the information known in June 1988). Defendants also implicitly take the position that fragmentation of the stones to much smaller sizes constituted "success" in the machine's usage, rather than complete stone removal as plaintiffs contend.

Plaintiffs have presented no evidence that this statement was false or misleading at the time it was made. In a March 24, 1989 letter to Medstone, the FDA indicated that "fragmentation of gallstones does not itself provide a clinical benefit, and that 'stone-free status' should be the criterion for effectiveness." (Plaintiffs' Ex 49 at 50). However, there is no evidence before the Court that there had been a definitive determination of what constituted "successful" lithotripsy treatment for gallstones 'as of the date the registration statement became effective. Accordingly, the Court denies summary judgment with regard to this statement.

b. *"from 20,000,000 to 25,000,000 persons suffer from gallstone disease, and El from 500,000 to 600,000 gallstone operations are performed annually in the United States. The Company believes that in the coming years a substantial number of the treatments involving gallstones will be made with lithotripters . . . £ its] marketing plan is based on the belief that within the next 5 to 10 years there will be a total of 2,000*

> *lithotripters installed in the United States which will be used to treat kidney and gallstone patients." (Ex 124 at 14)*

Plaintiffs contend that this is misleading because: (1) it implies that the total 20,000,000 to 25,000,000 population of people afflicted with gallstones could potentially undergo lithotripsy, which is false in light of experts' Dr. Fromm and Greenberger's testimony that only 10-15% of symptomatic gallstone patients are eligible for such treatment (Fromm Tr. at 133-34; Greenberger Tr. at 68); and (2) the "belief" that 2,000 lithotripters would be installed in the United States was (a) not reasonable in light of the saturation of the renal market (exemplified by defendant Rose's September 1988 "It's dead" remark) and the shaky preliminary results on the gallstone trials as well as (b) inaccurate, especially in light of the fact that this statement was prepared by Weeden with the assumption that FDA approval for gallstone use would be forthcoming and without the benefit of the specific clinical data from the Medstone test results. *See* Weeden employee Sabino's deposition Tr. at 79, 83, 229; Weeden Report, Ex 121 at 16 ("[r]eports of German clinical trials have been promising, with repeated success rates of about 80% ... Medstone success rates have been at least comparable, according to a Medstone investigator.").

Defendants counter that the statement is not misleading, since it indicates only that a portion of the 500,000 to 600,000 surgeries could be replaced with lithotripsy treatment, not that all 20,000,000 people afflicted with gallstones would be treated with lithotripsy. Moreover, defendants point out that the registration statement does disclose that "the number of lithotripsy-treatable patients is unknown." (Ex 124 at 16). They contend that disclosure of gallstone patient lithotripsy eligibility would have been premature in June 1988, since clinical trials of the procedure were just getting underway.

With regard to the "2,000 lithotripters in U.S." statement, defendants counter that: (1) plaintiffs have produced no evidence in existence at the time of the registration statement which indicates that the renal market was then saturated; (2) the preliminary clinical data for gallstone lithotripsy was not "dismal" at the time of the registration statement's issuance; and (3) de-

fendants did not withhold crucial information from Weeden and the Wilkerson Group during their preparation of reports on the company in anticipation of the June 1988 public offering. Indeed, defendants indicate that they did not have preliminary test results to disclose at that time. (The Wilkerson final report was issued in April 1988 and the Burke memo detailing the clinical results is dated May, 1988).

The Court denies plaintiffs' motion with regard to this statement as well, given plaintiffs' failure to provide evidence of its misleading nature in light of *facts known or available at the time the statement was made.*

c. *"Due to the receipt of [an IND/IDE for gallstone clinical studies and a PMA for kidney lithotripters], the Company anticipates additional sales of its System in future periods." (Ex 124 at 12)*

Plaintiffs argue that this is misleading because it fails to disclose that the renal market was saturated or that Medstone's business plan was totally dependent on FDA approval of the use of lithotripsy for the treatment of gallstones. Plaintiffs also contend that it is misleading because it does not indicate that the IND/IDE site sales would not recur absent FDA gallstone approval, and that the prospect of such FDA approval was very slim in light of the preliminary clinical results. Plaintiffs cite only to the deposition testimony of stockbroker Peck Hayne, Tr. at 117, in which he indicates that he found out after the offering that the IDE sales were "non-recurring."

Defendants counter with (1) the declaration of defendant Radlinski, in which he asserts that "Medstone assumed in its internal business plan that it would continue to sell the System for use in the treatment of kidney stones" to refute the contention that gallstone sales success was the *sine qua non* of Medstone's monetary success and (2) Medstone's disclosure on the sixth page of the prospectus that "[u]nder the IND/IDE, the System may only be used at seven locations within the United States. To date the System has only been used at one hospital on a limited number of patients. No assurance can be given that the clinical trials for use of the System in the treatment of patients with gallstones under the IDE/IND will be successful."

The Court denies summary judgment on this statement as well, in light of plaintiffs' failure to produce evidence that facts available at the time this statement was made would have indicated its falsity.

d. *"Revenues are recognized for financial accounting purposes in accordance with the underlying contractual terms of each sale. Typically, contract terms specify the transfer of title upon shipment, substantial completion or installation of the Device, or acceptance by the customer." (Ex 124 at F-9).*

Plaintiffs urge that this statement was false and misleading at the time it was made, in light of defendants' nondisclosure of their intent to enter into contracts which followed "bill and hold" sale practices. Defendants counter this claim by pointing out that plaintiffs have offered no evidence of defendants' *intent* to enter into such transactions. In light of plaintiffs' failure to produce evidence to support defendants' purported intentions, the Court denies them summary judgment as to this statement.

e. *"In connection with this offering, the Company's shareholders and option and warrant holders have agreed that they will not, without the written consent of the Underwriter, sell or otherwise dispose of any shares of the Company's Common Stock that are presently outstanding . . . for a period of six months from the date of this Prospectus." (Ex 124 at 34)*

Plaintiffs argue that this claim is also misleadings because it does not indicate that at the time of the public offering, defendants Payne and Penfil intended to dispose of their stock after the 90-day statutory prohibition on insider trading had run (i.e., less than 6 months after the offering). Defendants Counter that plaintiffs provide no evidence of such intent except the sales themselves, and point out that Payne and Penfil acted in accordance with the procedure set out in this statement: they got the approval of the underwriter before consummating their sales. Moreover, defendants produce declarations of Payne and Penfil, in which they state that they had no such intent to sell their stock at the time of the public offering. In light of plaintiffs' failure to

produce any evidence of Payne and Penfil's intent to sell, the Court denies summary judgment as to this statement.

f. *"The initial public offering price has been determined by negotiation between the Company and the underwriter." (Ex 124, at 8)*

This statement is misleading, plaintiffs argue, because it implies that the price was obtained through a true "hammering out" process of negotiation, when in fact Weeden, the underwriter, was inexperienced at such stock offerings and had performed little investigation or due diligence into Medstone's profitability, other than that information which was fed to it by Medstone personnel. To support their argument, plaintiffs point to Weeden's deposition admission that the Medstone offering was the first and last public offering underwritten by the company (Weeden Tr. at 53) and the "due diligence binders" used by attorney Newby during his due diligence (Exs 128 and 129).

Defendants counter that (1) Don Hill, the head of corporate finance at Weeden, had participated in 40 public offerings during his career; and (2) the due diligence binders used by Newby were not Weeden's sole efforts towards due diligence, as exemplified by the Wilkerson Group report and Hill's participation in meetings with Medstone executives.

Plaintiffs have not produced evidentiary support for their contention that this statement is false. Accordingly, the Court denies plaintiffs' motion with regard to it.

g. *Loss of Key personnel, such as Errol Payne, "would [have] an adverse effect on the Company's business prospects." (Ex 124 at 7)*

Plaintiffs urge that this statement is misleading, since Payne in fact intended to leave the company at that time. Plaintiffs point only to the Payne Tr. at 21, where Payne states that he left the Company shortly after the offering, to support their contention that he had the intent to leave at the time of the offering. This is insufficient evidence of Payne's intent to leave at the time of the registration statement's issuance. Accordingly, the Court denies

plaintiffs' motion for summary judgment with regard to this statement.

h. *"[T]here can be no assurance that necessary [FDA] clearances in ill be granted to the Company." (Ex 124 at 6)*

Plaintiffs argue that defendants should have particularized the risk factors involved more in this statement, in light of the mediocre preliminary clinical trial results, citing *In re Fortune Systems*, 680 F. Supp. 1360 (N.D. Cal. 1987), for the proposition that such "known adverse facts" must be revealed with particularity instead of as hypothetical risks. Defendants aptly point out that at the time this statement was made, however, it was not a "known adverse fact" that FDA gallstone approval would not be forthcoming and therefore no further disclosure need have been made. In light of plaintiffs' lack of evidence that FDA non-approval was a "known fact" at the time of the registration statement's issuance, the Court denies plaintiffs' motion with regard to this statement.

i. *"The Company['s] . . . near-term revenues will depend on its success in marketing the Medstone System . . ."*

Plaintiffs allege that this risk factor was not sufficiently particularized, since defendants failed to disclose that Medstone's entire business plan was contingent on gaining FDA gallstone approval. However, they produce no evidence to support this proposition. Accordingly, the Court denies plaintiffs summary judgment on this point.

4. ***Materiality of the Misstatements***

Plaintiffs argue that the above statements are also material, because "there is a substantial likelihood that a reasonable investor would attach importance [to these statements] in determining whether to purchase the security registered." 17 C.F.R. § 230.405. Plaintiffs contend that these statements are proven to be material by the fact that defendants included unspecified "related information" in communications with the SEC. Defendants argue that plaintiffs have pointed to no evidence which would indicate that these statements are material. The Court declines to

rule on the statements' materiality in light of its denial of plaintiffs' motion as to all statements on the element of falsity.

5. ***Defendants' Due Diligence Defense***

Finally, plaintiffs argue that they should be granted summary judgment since defendants cannot establish a "due diligence" defense. This Court does not reach this issue here, however, in light of its denial of plaintiffs' motion on other grounds.

E. Defendant Freeman Rose's Motion

1. ***Section 10(b)***

a. *Rose's allegedly misleading public statements*

(1) November 11, 1988 Press release: "Our gallstone investigations are progressing as expected and our competitive position remains strong."

Rose argues that summary judgment should be granted on this claim in his favor because plaintiffs have failed to produce evidence of its falsity. Plaintiffs contend that it was misleading, given the preliminary clinical results of fragmentation (instead of stone-free status) in patients and Rose's own admission in September 1988, in response to the question "is the kidney market near saturation," that "it's dead."

As discussed with regard to plaintiffs' motions above, plaintiffs have produced no evidence that this statement was false at the time it was made. No standard for what constituted success had been set at that time. The FDA letter to Medstone indicating that it considered that only "stone-free" status constituted success was written later, in May 1989. Moreover, the status of the renal market is inapposite to this statement, since it only discusses biliary market competitiveness. In light of plaintiffs' failure to produce evidence, the Court grants Rose summary judgment with regard to this statement.

(2) March 5, 1989 letter to shareholders in 1988 annual report: "The FDA granted us permission . . . to determine the safety and effectiveness of the Medstone STS for the treatment of gallstones. Progress is excellent."

Rose argues that plaintiffs have produced no evidence to support their claim that this is a false statement in that it indicates that final FDA approval will be granted with the similar ease with which it was granted for kidney treatment. Rose points out other information already existed in the marketplace, issued by Medstone, which would counteract any such impression. Rose points to (1) the rest of the Annual Report (Plaintiffs' Ex 354 at 13), where it indicates that "no assurances can' be given as to when or if a gallstone PMA will be issued for the system;" and (2) various warnings in the June 1988 prospectus, such as "[n]o assurance can be given that the clinical trials for the use of the System in treating patients with gallstones under the IND/IDE will be successful" (Ex. 124 at 6). Read in light of the information then available in the market, the statement does not appear misleading. Accordingly, the Court grants summary judgment in favor of Freeman Rose on this statement as well.

(3) May 2, 1989 Press release: "we see increased sales activity . . . the market is responding favorably to Medstone's Dual Imaging Therapy System."

As mentioned with regard to plaintiffs' summary adjudication motion with regard to this statement (*see* Appendix A, section f), plaintiffs have failed to produce evidence to support their argument that this statement was false at the time it was made. In light of this lack of evidence, the Court grants Rose summary judgment on this claim as well.

2. ***Scienter***

Rose presents his own declaration, in which he states that he made all these statements in good faith, to prove that he lacked the requisite scienter. In rebuttal, plaintiffs present no evidence to support a finding of scienter. Instead, they rely on information which was only available after the statements were made to prove their claim that Rose "must have known" that these statements would mislead readers at the time he made them. However, in

light of the Court's grant of summary judgment on the basis of plaintiffs' failure to produce evidence of the statement's misleading nature, the Court need not reach defendant's contention that he lacked scienter.

3. *"Controlling Person" Liability for Section 10(b)*

Rose denies that he is subject to liability under Section 20(a) of the 1934 Act, which states: "[e]very person who, directly or indirectly, controls any person liable under any provision of this title or any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a). "Control" has been defined by the SEC as "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through ownership of voting securities, by contract, or otherwise." 17 CFR § 230.405.

In order to establish Rose's liability as a controlling person, plaintiffs must provide evidence that (1) Rose had actual power or influence over Medstone (and the other defendants) and (2) Rose was a "culpable participant" in the alleged securities violations. *Orloff v. Allman*, 819 F.2d 904, 906 (9th Cir. 1987). Once plaintiffs establish these two things, then the burden shifts to the defendant to prove the good faith defense. *Hollinaer v. Titan Capital Coro.*, 914 F.2d 1564, 1575 (9th Cir. 1990).

Plaintiffs argue that, due to his position and his subsequent leadership of the day-to-day operations of Medstone, Rose had the power to influence the other defendants. Plaintiffs cite *Wool v. Tandem Computers. Inc.*, 818 F.2d 1433, 1441 (9th Cir. 1987) for this proposition. Under *Wool,* in such a small company as Medstone, Rose's participation in the day-to-day affairs of the company during the class period combined with his officer position may be sufficient to support a finding of Rose's actual power or influence. However, plaintiffs have not provided any evidence to support the contention that Rose was a culpable participant in the violations allegedly perpetrated by the other defendants. In light of plaintiffs' failure to produce evidence with regard to

Rose's status as a "culpable participant" in the remaining alleged security fraud violations, the Court also grants Rose summary judgment on the "controlling person" issue.

4. *Section 11 claim*

Plaintiffs state that they do not oppose Rose's motion for summary judgment on this claim. Given plaintiffs' nonopposition, the Court grants Rose's motion as to this claim.

F. **Plaintiffs' Motion to Strike**

Plaintiffs seek to strike the declarations of Freeman Rose, Errol Payne, Richard Penfil and David Radlinski offered in support of defendants' motions for summary judgment. Plaintiffs contend that these declarations are self-serving and contradictory of the declarants' deposition testimony. In their depositions, these defendants stated that they could not recall discussing certain statements contained in the registration statement; in their declarations, defendants state that they acted in good faith and believed these same statements to be accurate at the time they were included in the registration statement. Moreover, plaintiffs argue that the declarations contain inadmissible hearsay, since some of the statements contained in them are not based on the declarants' personal knowledge. *See. e.g.,* Penfil decl. at ¶ 14-16, Radlinski decl. at ¶ 3, Rose decl. at ¶ 8, 10.

Plaintiffs argue that the declarations contain bald allegations of ultimate facts and legal conclusions and therefore cannot be used to support a summary judgment motion, citing *Galindo v. Precision American Corp.,* 754 °F.2d 1212 (5th Cir. 1985). In particular, plaintiffs contend that conclusory affidavits by parties purporting to set forth their state of mind do not satisfy a party's burden -in moving for summary judgment, citing *United States v. One Single Family Residence, Miami, Fla.,* 683 F. Supp. 783, 789 (S.D. Fla. 1988). Moreover, plaintiffs point out that such professions of good faith are irrelevant to the section 11 claims, since all that plaintiffs need prove under that section is that the registration statement contained material misrepresentations.

Defendants counter that declarations of good faith are sufficient to establish a lack of scienter under Section 10(b), referring to *In*

re Apple, 886 F.2d at 1117. Moreover, they urge that the professions of good faith are also relevant to the section 11 claim, in order to establish that allegedly false forwardlooking statements and opinions were not misleading. Id. at 1113. Finally, defendants contend that the declarants' alleged "hearsay" statements in fact are not hearsay, as they are not offered to prove the truth of the matter asserted, but only to show their effect on the particular declarant's state of mind.

Defendants also seek to counteract plaintiffs' citation of *One Single Family Residence*. They point out that the case dealt with the affidavit of a claimant with regard to his state of mind, which was held insufficient to establish that he did not have actual knowledge. Defendants argue that this case merely reinforces the necessity for plaintiffs to come forward with evidence of defendants' scienter in order to avoid summary judgment on the section 10(b) claim. Moreover, defendants' citation to *Apple* is apt: the affidavits there were direct professions of good faith put forth by defendants themselves to establish that their statements were accurate and not misleading. 886 F.2d at 1117.

The Court denies plaintiffs' motion to strike. Plaintiffs' objection are not well taken, and the declarations at issue do not directly contradict the declarants' deposition testimony, as plaintiffs contend.

G. Defendants' Motion to Strike Plaintiffs' Declarations

Defendants move to strike the declarations of Douglas Campion, Tracy Thrower and John Torkelson submitted by plaintiffs in opposition to defendants' summary judgment motions. Defendants Contend that the declarations of plaintiffs' counsel Thrower and Campion are argumentative and conclusory. Campion purports to have reviewed the declarations of Radlinski, Penfil, Payne Andrifiose and other evidence in the case, and places side-by-side the declarants' offending statement and evidence available at the time which would defy their protestations of good faith; Thrower provides a summary of the sixty articles regarding lithotripsy provided by defendants which were available during the class period and determines that they could not have credibly reached analysts. Defendants argue that plaintiffs submitted these declara-

tions to augment their legal arguments and thus Circumvent the 35-page brief limit.

Defendants also challenge the declaration of Torkelson, plaintiffs' damage expert, in which he offers his "expert opinion regarding the dissemination of information to and absorption of that information by the investment community concerning Medstone's prospects and gallstone lithotripsy in general." Defendants argue that such testimony goes beyond Torkelson's expert witness designation into an opinion on causation, not just damages. Since Torkelson has no personal knowledge of the facts he bases his opinion on, and the testimony is not within his capacity as an expert, the declaration should be stricken, defendants urge. Defendants point to Torkelson's testimony in other actions with regard to aspects which over-reach his expert witness designations, some of which are described in *In re Fortune Systems Sec. Litigation*, 680 F. Supp. 1360, 1367-68 (N.D. Cal. 1987).

Plaintiffs counter that all of these declarations are based on the personal knowledge of the declarants, as they have all personally reviewed the documents they discuss.

The Court grants defendants' motion, except to the extent plaintiffs' counsel provide evidentiary foundation for certain discovery documents and records. However, the Court has considered the arguments in the Thrower and Campion declarations, albeit they are based on the declarants' review of the same documents that the Court has been required to consider in deciding these motions. The Torkelson declaration exceeds the bounds of Torkelson's expert designation. Even were his opinions accorded weight, however, they could not enhance the materiality of statements that plaintiffs rely on nor undermine the circulation of relevant information in the market place. Accordingly, the Court grants the motion as to the Torkelson declaration.

H. Defendants' Prospectus Motion

Defendants move for summary judgment under Section 11 on the basis that the prospectus contains no misleading statements. They group plaintiffs' alleged misstatements and omissions into three categories: (1) those with regard to the adverse effects and efficacy of gallstone lithotripsy (the "clinical information issue");

(2) those factors adversely effecting the size of the future market for lithotripters (the "market issue") and (3) those regarding defendants' non-compliance with two federal regulations concerning x-ray equipment attached to the lithotripter when used for kidney treatment purposes (the "non-compliance issue").

1. ***The X-Ray Table Regulations***

Plaintiffs allege that the prospectus was misleading for failing to disclose that "Medstone was experiencing serious and continuing problems in its X-ray imaging system . . . Medstone was not in compliance with the FDA's requirements." (Complaint 74(a)). Defendants argue that there were not enough facts available to warrant disclosure as of the date of the prospectus' effectiveness and that, at any rate, the information is not material. Defendants point out: (1) that they first suspected that the x-ray table may not have complied with 21 CFR § 1002.10 and § 1020.30(n) in June 1989 (Lyons decl.) and (2) the FDA did not determine until July 1989 that defendants were in fact not in compliance with FDA regulations (Lyons decl.). Moreover, the FDA found that Medstone was in compliance as of August 1989; it did not officially approve defendants' new design plan until September 1991, however. (Lyons decl.).

Furthermore, defendants argue that even if the non-compliance had been known at the time of the prospectus' issuance, it need not have been disclosed since it was not material. They contend that neither of the noncompliances had any effect on the FDA approval process of the lithotripter for biliary usage, and were relatively minor technical non-compliances which could have been and were easily corrected. Since these non-compliances did not have a significant impact on the company, then, defendants claim they were immaterial and need not have been disclosed. *See In re Convergent,* 948 F.2d at 516 ("a company need not detail every corporate event, current or prospective").

In light of plaintiffs' failure to produce evidence that the non-compliance was known at the time the prospectus became effective, the Court grants defendants' motion as to this alleged omission.

2. ***Gallstone Lithotripsy***

Defendants urge that clinical information with regard to gallstone therapy was speculative as of the effective date of the registration statement, and therefore need not have been disclosed. They contend that (1) the patient eligibility percentages for gallstone lithotripsy treatment were not known as of June 1988, citing the Weeden report which stated that, based on its survey of hospital administrators and doctors, the eligibility estimates ranged from 2% to 70%; (2) the efficacy of the machine was also not known, since clinical trials in just one hospital had recently begun, and (3) per plaintiffs' expert, Dr. Way, gallstone lithotripsy has no adverse side effects to disclose.

Moreover, defendants argue that the information was not material because (1) other investigatory and preliminary data was already in the marketplace, such as the February 1988 article re: the clinical gallstone lithotripsy testing being conducted in Germany (Defendants Ex 1677); and (2) the prospectus itself stated that "the percentage of lithotripsy-treatable patients is not presently known."

The Court grants defendants summary judgment as to these alleged omissions, in light of the clinical trial results' speculative nature at the time of the registration statement's issuance and defendants' consequent lack of duty to disclose. *See Convergent*, 948 F.2d at 516.

3. ***Factors Affecting the Size of the Lithotripsy Market***

a. *Statement 8: "within the next 5 to 10 years, there will be a total of approximately 2,000 lithotripters installed in the united States which will be used to treat kidney stone and gallstone patients."*

Defendants state that such forward-looking statements are not actionable where the statement is (1) genuinely believed; (2) reasonably believed; and (3) the speaker is not aware of any undisclosed facts tending to seriously undermine the accuracy of the statement. *In re Apple*, 886 F.2d at 1113. *Cf. Virginia Bankshares, Inc. v. Sandbera*, 111 S.Ct. 2749 (1991) (such statements are actionable under Section 14 of the 1934 Act under some circumstances). They cite to the Wilkerson report, created

for Weeden in its performance of due diligence, which stated that this was a "conservative estimate based on a straightforward, break even analysis taking into account only those patients who are very clear candidates today. These are symptomatic patients with small, solitary stones in the kidneys, upper ureters or gall-bladder." This estimate was reached after Wilkerson employees met with doctors, Medstone competitors, FDA representatives and Medstone personnel, as indicated in the "Methodology" section of the report.

b. *Statement 10: system has been used "successfully to treat . . . gallstone patients since January 1988"*

Defendants also claim that this statement was true when made, as the device had been used to treat gallstone patients since that time in the preliminary clinical trials. Moreover, this statement was not misleading because the prospectus indicated elsewhere that the usage of the machine for gallstone treatment was minimal (i.e., had only been used in one hospital for clinical trials).

c. *No Duty to Disclose related omissions because they were available elsewhere in the marketplace or were not ripe for disclosure, and therefore were not material.*

Defendants argue that: (1) information regarding the safety and efficacy of gallstone lithotripsy was not ripe ford disclosure in 1988, since the results were only in their preliminary stages, Citing *In re Converaent*, 948 F.2d at 516 (if estimates not made with reasonable certainty, they may not even be allowed to 'be disclosed to the public); (2) plaintiffs have produced no evidence that kidney lithotripter treatments were known to have' adverse side effects as of the date of the prospectus statement; (3) the kidney lithotripter market was not saturated as of June 1988, so there was no need to disclose that "fact;" (4) the possibility that smaller hospitals may choose not to purchase lithotripters, which was mere speculation on Wilkerson's part, and therefore did not need to be disclosed either; and (5) there was no need to disclose the possibility that gallstone marketing expenses would exceed those for kidney usage and therefore result in lower profit margins, since defendants did not even know whether this would be true or not at the time of the registration statement.

The Court grants defendants summary judgment as to these statements with regard to the lithotripsy market, since the alleged omissions were not ripe for disclosure and the allegedly false statement no. 10 was not misleading when read in context. See Id. (no need to disclose speculative information).

4. ***Weeden's Due Diligence Defense***

Defendants argue that they have shown both that Weeden conducted a reasonable investigation and that Medstone held a reasonable and actual belief in the truth of the statements put forth in the registration statement. They point to the due diligence binders which Newby used to conduct legal due diligence, the Wilkerson report and the meetings between Medstone officers and Weeden corporate financial officer Don Hill.

Plaintiffs claim that Weeden's investigation did not constitute a "reasonable investigation" by an independent auditor, since (1) Newby had a conflict of interest, as he was negotiating with Medstone for a position as Hong Kong distributor for lithotripters and (2) the Wilkerson report was based on interviews with Medstone officers with regard to the clinical trial results on the gallstones. The Court declines to grant defendants summary judgment on this defense because a material issue of fact remains with regard to the reasonableness of Weeden's investigation.

5. ***Devere Section 11 standing***

In order to establish standing to assert a Section 11 claim, each plaintiff must allege and prove that his stock was issued pursuant to the particular registration statement alleged to be defective. *See Guenther v. Cooper Life Sciences, Inc.*, 759 F. Supp. 1437 (N.D.Cal. 1990); *Abbey v. Computer Memories, Inc.*, 634 F. Supp. 870, 872 (N.D.Cal. 1986). Defendants contend that they should be granted partial summary judgment with regard to class representative Thomas Devere and his class members on the Section 11 claim, since Devere purchased his stock in the open market in May and June 1989 and has not produced evidence to indicate that his shares originated in Medstone's original public offering. The Court agrees and grants defendants summary judgment with regard to Devere's Section 11 claim.

6. *Prospectus Statements and Secondary Liability*

Defendants seek summary judgment on the Section 10(b) claims on the basis that plaintiffs have failed to prove scienter. In this circuit, scienter is established by recklessness, or "an extreme departure from the standards of ordinary care, . . . which presents a danger of misleading buyers or sellers . . . that is so obvious that the actor must have been aware of it." *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990) (citations omitted). Plaintiffs have failed to carry their burden and show such evidence of scienter. Accordingly, the Court grants defendants summary judgment with regard to the Section 10(b) prospectus allegations.

Defendants argue that if summary judgment is granted on the Section 11 and Section 10(b) claims with regard to the prospectus, then summary judgment as to all secondary claims (i.e., controlling persons and conspiracy) should be granted as well. The Court agrees and grants summary judgment in favor of defendants as to secondary liability for all these statements.

7. *Those Members of the Class Suffering no Damages Under § 11*

Defendants argue that summary judgment should be granted on the Section 11 claim against those class members who bought stock at the offering price and sold it for the same price or more, since they suffered no damages. The Court grants this portion of defendants' motion. Admittedly, difficulties may be involved in ascertaining which members of the plaintiff class are subject to this order, but logically these are not investors who suffered "damages."

8. *Costs & Attorneys Fees on § 11 claim*

Defendants claim that costs and fees pursuant to § 11(e) should be awarded due to the unfounded and frivolous nature of plaintiffs' Section 11 claims. The Court denies defendants' request, because plaintiffs' claims are not so groundless or frivolous as to warrant sanctions.

I. Defendants' Post-Prospectus Motion

1. *Omissions Excused Because the Allegedly Omitted Information was "credibly available to the market through other sources."*

Defendants argue that they should also be granted summary judgment with regard to the Section 10(b) claim to the extent it is based on their post-prospectus statements. Plaintiffs rely on the fraud on the market theory (Paragraph 94 of Complaint) in order to satisfy the "reliance" element of Section 10(b). "Under the fraud on the market theory, the plaintiff has the benefit of the presumption that he has indirectly relied on the alleged misstatement, by relying on the integrity of the stock price established by the market." *In re Apple Computer*, 886 F.2d at 1114 (citing *Basic, Inc. v. Levinson*, 108 S.Ct. 978 (1988)). In a fraud on the market case, "the defendant's failure to disclose material information may be excused where that information has been made credibly available to the market by other sources." *Id.* at 1115.

Defendants contend that they need not have disclosed information regarding the safety and efficacy of gallstone lithotripsy, the possibility of gallstone recurrence or other negative factors regarding the lithotripsy market since other sources in the market made the information available. Principally, they point to 60 articles in trade journals, newspapers and newswires. *See* Appendix to Defendants' Reply. For example, they cite a July 1989 New York Times article which outlined the possible concerns with gallstone lithotripsy causing increased blood pressure and harming kidney tissue; an April 1989 USA Today issue, which indicated the clinical gallstone results released by one hospital participating in the Medstone studies; a March 1989 Los Angeles Times article which indicated that gallstone recurrence was a possibility with lithotripsy; a March 1986 article in the New England Journal of Medicine which indicated that clinical selection criteria for gallstone lithotripsy was restrictive; and a 1987 AP Newswire which indicated that "as lithotripters proliferate, hospitals will have to charge a lot just to break even."

Defendants urge that these 60 articles were "transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression." *In re*

Apple Computer, 886 F.2d at 1116. In Apple, 20 articles, some in trade journals, were found to have credibly reached the market to sufficiently counterbalance any misleading impression created by the defendants' omissions.

Moreover, defendants contend that Medstone's non-compliance with technical regulations regarding its xray machines was not material because it had little impact on the company. Alternatively, defendants contend that even if such x-ray information was material, it was disclosed to the investing public in a timely manner: in a press release six days after defendants received the formal letter from the FDA notifying them of such non-compliance.

Plaintiffs counter that the holding in *Virginia Bankshares, Inc. v. Sandberg*, U.S. , Ill 5. Ct. 2749, 2755 (1991) applies here: that "knowingly false statements of reasons may be actionable even though conclusory in form Plaintiffs also point to the case's comments that "not every mixture of [the false] with the true will neutralize the deceptive" and that "[i]f it would take a financial analyst to spot the tension between the [truth] and the [falsity], whatever is misleading will remain materially so, and liability should follow." Id. at 2760. Nonetheless, they argue that defendants should lose even if the standard they espouse is applied.

Plaintiffs argue that the 60 articles did not "credibly reach" the marketplace because they were contained in newswires and "poorly-circulated or lightly-regarded publications," and the press was not actively scrutinizing either Medstone or biliary lithotripsy as it was Apple. Plaintiffs reinforce that the *Apple* holding was expressly limited to similar facts: "we stress the limits of our holding. Scrutiny by the press will not ordinarily excuse the type of unqualified exuberance expressed by Apple . . . Even in a fraud on the market case, corporate insiders are not relieved of the duty to disclose material information where that information has received only brief mention in a few poorly circulated or lightly regarded publications." 886 F.2d at 1116. Moreover, plaintiffs assert that Medstone was an unknown company, the first in its field of lithotripsy to go public, so that the public necessarily relied more heavily on the statements of its insiders and more of a barrage of press scrutiny would be required to neutralize them compared to the scrutiny in *Apple*.

Plaintiffs also argue that the articles' information did not "credibly reach" the market and effectively counterbalance the statements made by defendants because the majority of them were small, non-feature articles. Plaintiffs rely on the declaration of their damages expert, Torkelson, in order to refute the contention that the material credibly entered the market. The Court has ordered this declaration stricken, however, and therefore does not consider the declaration in its analysis of defendants' motion here. *See* discussion, p. 31.

Defendants neutralize plaintiffs' argument that the *Virginia Bankshares* analysis should apply, by pointing out that the case was decided within the context of section 14(b) of the 1934 Act, a claim for a false and misleading proxy statement, which does not involve a "fraud on the market" theory approach. Moreover, the quotations excised by plaintiffs referred to whether "publishing accurate facts in a proxy statement can render a misleading proposition [in the proxy] too unimportant to ground liability on." 111 S.Ct. at 2760. Accordingly, they urge that the *Apple* materiality approach should be applied here.

Defendants further argue that plaintiffs' argument is inherently contradictory, since they at once plead the fraud on the market claim and thereby profit from the presumption that the market functions efficiently and yet content that the market did not function efficiently with regard to these articles. Moreover, they contend that (1) financial analysts have access to newswires, and analysts in turn input their two cents into the marketplace for it to process and (2) trade journal publications were relied on by the *Apple* court in making its materiality determination (Ex 1775 at 41-52), although 21 of the articles put forth by defendants here were from national newspapers.

The *Apple* materiality standard applies. Moreover, defendants have established the statements' immateriality under that standard. Accordingly, the Court grants summary judgment in their favor on the materiality element.

2. ***Scienter***

Defendants also argue that plaintiffs have failed to establish scienter, or "reckless conduct [which] may be defined as a highly

unreasonable omission, involving . . . an extreme departure from the standards of ordinary care." *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990). Defendants point to their declarations which indicate that they had a good faith belief in the veracity of the allegedly misleading statements at the time they were made. They point out that in *Apple*, the court found such declarations sufficient to support summary judgment on the scienter element in Section 10(b) where plaintiffs presented no contradictory evidence. 886 F.2d at 1117.

Moreover, defendants contend that their actions at the time substantiate these declarations: they moved operations to a bigger, more expensive site in May 1989; they increased the size of their inventory until October 1989 and correspondingly increased their number of personnel; the company entered into an international distribution agreement with GE; a June 1989 internal memorandum from Penfil to Rose stated "[t]he meeting with the FDA was extremely beneficial and I feel, . . . [it] could not have come out better for Medstone." In *Apple*, such a massive investment into the Company's product was deemed indicative of good faith. 886 F.2d at 1117.

Halyana Breslawec, the FDA Doctor who oversaw the whole approval process, even indicated at a medical conference in May 1989 that she expected gallstone lithotripsy to be approved within the next year or so.

Defendants contend that Penfil and Payne's stock sales 90 days after the public offering are not indicative of scienter, either. Defendants submit the declarations of Payne and Penfil, in which they indicate their independent personal reasons for selling the stock. Payne explains that he sold the stock concurrent with his departure from the company. Penfil explains that he wanted to resign from Medstone so that he could spend more time with his growing young family, and in order to ensure financial stability upon resignation, he sold the stock. In *Apple*, the Ninth Circuit stated that "[t]he pattern of stock trading by . . . insiders is insufficient to raise an issue for the jury [with regard to bad faith] . . . [where] [u]ncontradicted . . . testimony from . . . the defendants provide[ ] credible and wholly innocent explanations for the stock sale." 886 F.2d at 1117.

Plaintiffs rely on allegedly misleading statements which underlie their summary judgment motions in order to support their scienter claim. Moreover, plaintiffs argue that defendants' contemporaneous actions only indicate their conspiracy to make the company look good to investors, not their good faith; the memo from Penfil to Rose only shows Penfil's attempt to allay Rose's fears re: FDA approval; and defendants make an insufficient showing that it is reasonable to have relied on the statement of FDA personnel. (They also offer the deposition of ex-FDA employee Frank Casciani, defendants' expert, in which he states that he told Medstone officers that the gallstone lithotripter was approvable, in his opinion, Tr. at 181.)

Finally, plaintiffs argue that the stock sales alone, since they are so close in time to the offering, are indicative of scienter.

Since plaintiffs have not met their burden of producing sufficient evidence of scienter, the Court grants defendants summary adjudication with regard to this element of plaintiffs' 10(b) claims.

3. ***"Controlling person" and conspiracy claims***

Defendants argue that if summary judgment is granted on the Section 11 and Section 10(b) claims with regard to postprospectus statements, then summary judgment as to all secondary claims (i.e., controlling persons and conspiracy) should be granted as well. The Court agrees and grants summary judgment in favor of defendants as to secondary liability for all these statements.

4. ***Class Members selling shares in a "short position"***

Defendants argue that they should be granted summary judgment as to all class members who sold their stock "short," i.e., those who committed to selling Medstone shares without actually owning them, in the belief that the market had overestimated the stock's value. Defendants conclude that such individuals should not now be allowed to rely on the fraud on the market theory, which is based on a presumption of the integrity of the market, when they relied on the opposite premise when they invested in the stock. Defendants' position is persuasive, but the Court finds

it unnecessary to reach this issue in light of its grant of defendants' summary judgment motions on other grounds.

III. CONCLUSION

1. The Court denies plaintiffs' motion for summary adjudication of their Section 10(b) claim. The misstatements on which plaintiffs base this motion were not alleged in the complaint. The Court, therefore, does not need to reach the merits of the motion.

2. The Court denies plaintiffs' motion with regard to their Section 11 claim. The Court finds that defendants were given adequate notice to prepare an answer for the alleged misstatements on which plaintiffs base this motion due to the allegations contained in Paragraph 85 of the complaint, and therefore reaches the merits of the motion. *See Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). Plaintiffs have failed to sustain their burden of producing evidence that the alleged misstatements contained in the June 2, 1988 registration statement were false *at the time they were made.* 15 U.S.C. § 77k. Accordingly, the Court denies plaintiffs' motion for summary judgment. In light of the denial of plaintiffs' motion, the Court does not reach the issues of the materiality of the misstatements or defendant Weeden's due diligence defense.

3. The Court grants defendants' prospectus motion. Defendants had no duty to disclose in the prospectus: (1) information with regard to the alleged misstatements about the adverse effects and efficacy of gallstone lithotripsy; (2) factors adversely affecting the size of the future lithotripter market; or (3) defendants' noncompliance with two federal regulations concerning x-ray equipment attached to the lithotripter. The non-compliances did not have a significant impact on the company, and therefore were not material. *See In re Convergent Technologies Litigation*, 948 F.2d 507, 516 (9th Cir. 1991) ("a company need not detail every corporate event"). In addition, information with regard to the lithotripter's efficacy and factors adverse to the lithotripter market need not have been disclosed since data with regard to them was only in a preliminary stage at the time the registration statement became effective. *See Id.* (if estimates are not made with reasonable certainty, they should not be allowed to be disclosed to the public). Moreover, the Court finds that summary

judgment should be granted defendants on "controlling person" liability under Section 15 and the conspiracy claim. Accordingly, the Court grants defendants' motion for summary judgment.

4. The Court grants defendants' motion with regard to Section 10(b) liability and defendants' post-prospectus statements. Defendants' failure to disclose material information with regard to the safety and efficacy of gallstone lithotripsy, the possibility of gallstone recurrence after lithotripsy or other negative factors affecting the lithotripsy market because such "information ha[d] been made credibly available to the market by other sources," namely, sixty articles and newswire reports which appeared throughout the class period. *In re Apple Computer Securities Litigation*, 886 F.2d 1109, 1115 (9th Cir. 1989). Accordingly, the Court grants defendants' Section 10(b) motion with regard to post-prospectus statements on these subjects.

In light of the foregoing, the Court grants defendants summary judgment with regard to plaintiffs' claims for conspiracy and "controlling person" liabiiity under Section 20(a) as well.

5. The Court grants defendant Freeman Rose's motion for summary judgment. Plaintiffs have failed to produce evidence of the misleading nature of Rose's statements in a November 12, 1988 press release, a March 5, 1989 letter to shareholders and a May 2, 1989 press release. Plaintiffs have not presented evidence to support the Section 10(b) element of scienter. Accordingly, the Court grants defendant's motion with regard to the Section 10(b) claim. In light of plaintiffs' nonopposition to Rose's motion with regard to the Section 11 claim, the Court also grants Rose summary judgment on that claim.

Plaintiffs have also failed to produce evidence that Rose was a "culpable participant" in the alleged securities violations of the other defendants, which would support their claim that Rose was a "controlling person" within the meaning of Section 20(a) of the 1934 Act. Accordingly, the court grants Rose summary judgment on this ground as well.

6. The Court denies plaintiffs' motion to strike.

7. The Court grants defendants' motion to strike the declaration of plaintiffs' damages expert John B. Torkelson and the

declarations of Attorneys Campion and Thrower, except to the extent Campion and Thrower's declarations provide evidentiary foundation for certain documents and records.

IT IS SO ORDERED.

IT IS FURTHER ORDERED that the Clerk shall serve a copy of this Order on counsel for all parties.

Dated: May 4, 1992.

/s/
ALICEMARIE H. STOTLER
UNITED STATES
DISTRICT JUDGE

APPENDIX A

The Misleading statements and Omissions Plaintiffs Allege in Their Motion under Rule 56(d) Brought Pursuant to section 10(b), Rule 10(b)5

Plaintiffs sought summary adjudication with regard to the falsity of selected aftermarket statements issued by defendants. *See* Appendix to defendants' opposition. Plaintiffs did not seek a ruling on any other element of a Section 10(b) claim.

a. June 30, 1988 second quarter report to shareholders: "shockwave lithotripsy is a nev medical science that uses non-invasive, acoustical shockwaves to disintegrate kidney stones and gallstones. These non-surgical (no-incision) techniques are becoming the therapy of first choice for stone disease."

Plaintiffs argue that this statement was false and misleading because such therapy was not the one of first choice at the time, as evidenced by: (1) the testimony of plaintiffs' expert Dr. Way that patients shied away from the treatment for gallstones, partially because the alternative of gallbladder removal through surgery ensured a total cure whereas the lithotripter method involved a possibility of stone recurrence; (2) a May 1989, report by Medstone employee Mike Mesenbrink, in which he stated "Medstone/IDE sites have difficulty finding patients to treat . . ." (Ex. 282).

In opposition, defendants argue that this statement constitutes mere unactionable "puffing," or a vague expression of optimism which is not actionable, citing *In re Apple Computers Securities Litigation*, 672 F. Supp. 1552, 1571-72 (N.D. Cal. 1987), *aff'd in part and rev'd in part on other grounds*, 886 F.2d 1109 (9th Cir. 1989). They argue that the future phrasing, "are becoming," indicates an opinion or "soft information," which is not misleading under the securities laws where it is made with a reasonable basis and in good faith. *In re Apple*, 886 F.2d at 1113. Defendants contend that, in light of the success in the clinical trials which had just begun, and all the evidence available as of the time the statement was made, such an opinion was reasonable.

Defendants refute plaintiffs' evidence by stating: (1) since Dr. Way has never performed a lithotripsy, the basis for his opinion is unclear; (2) Dr. Way's comments referred only to the use of the lithotripter with respect to gallstones, not kidneys; (3) the May 1989 Mesenbrink memo is inapposite, since it contains information made available after June 30, 1988; (4) the May 1989 memo is inadmissible anyway since it has not been authenticated; and (5) that the statement in the May 1989 memo is misquoted and taken out of context, as it states that "[m]ost companies struggle to find patients to treat" because of the large market share enjoyed by the industry giant, Dornier.

Plaintiffs respond that defendants' argument suffers from a tendency to lump both renal (kidney) and biliary (gallstone) lithotripter usage information together. Plaintiffs argue that the June 1988 statement may be deemed "puffery" with regard to kidney lithotripsy, since that had already gained FDA approval and was gaining in popularity from wider use; however, the outcome of the recently begun clinical studies at the time indicated that the results with regard to gallstone lithotripsy were not as favorable as with kidney lithotripsy and that the likelihood of FDA approval (and subsequent widespread usage) for that purpose was therefore low. (Ex. 37). Plaintiffs also contend that whether or not Dr. Way has himself performed a lithotripsy procedure with respect to gallstones is unimportant, since he could form his opinions as a member of the relevant medical specialist community who has referred his patients to hospitals in order to have lithotripsy performed on them.

Defendants' position prevails. Plaintiffs have not established that there was information available *as of June 30, 1988* which would indicate that such a statement was misleading. A May 4, 1988 memo (Ex. 37) from Medstone employee Burke to Medstone officer and defendant Penfil indicates the results of the first phase of the gallstone study, conducted with a group of 34 patients (of which accurate and full data was available for only 27). Four of the 27 patients, or 15%, had fragments immediately which were less than 3 mm, a size which presumably could be passed naturally by the patient thereafter. Upon a second lithotripsy treatment, another patient had stones that small as well. The majority of the remaining patients had larger fragments, which

were smaller than but more than 50% the size of the largest pre-lithotripsy fragments inside them.

In addition, the Wilkerson Group, hired by defendant underwriter Weeden, produced a report on Medstone's prospects in April 1988. (Ex. 121). The report predicted that the United States market could support 2,000 lithotripters for both kidney and gallstone usage; and reported that "physician acceptance" of the treatment for gallstones was good, save for reservations about stone reformation or insufficient fragmentation so that the fragments would not pass naturally. The report concluded, under the "physician acceptance" section, that "[u]ltimately, the question is one of patient preference," and quoted to analymous individual (presumably a physician) who indicated that 'It's going to be up to the patient. Most people I know would prefer to come into the hospital on Monday, go home on Tuesday and return to work on Wednesday' (which is possible with the lithotripsy procedure as opposed to the surgical option).

Accordingly, at the time the statement was made, there were no adverse facts available to defendants which would have indicated that such a "forward-looking statement" about lithotripsy becoming the therapy of first choice was unwarranted or misleading. Under *In re Apple*, 886 F.2d at 1113, the projection that the procedure was "becoming" the treatment of choice could not at the time be undermined by adverse undisclosed facts and appeared reasonable based on the information available at the time and therefore is not an actionable expression of optimism under Section 10(b). The Court would deny plaintiffs' motion for summary adjudication of this statement's falsity.

b. Medstone's 1988 10-K published March 1989: "The increase in sales revenue principally resulted from the shipments of 19 Systems during 1988 compared to eight Systems shipped in fiscal 1987 and an increase in the average sales price per system." (Ex 368)

Plaintiffs argue that this statement is misleading because defendants "borrowed" sales from future periods in order to inflate the sales figures for the year and thereby encourage more people to buy Medstone stock. Five of the 19 "shipments" were "bill and hold" sales, where a customer agreed to purchase the goods but

the seller (Medstone) retained possession until the customer requested shipment to designated locations. Plaintiffs state that they do not ask for summary adjudication of the propriety of this "bill and hold" accounting practice under these circumstances; instead, they seek the Court's determination of Medstone's duty to disclose its usage of the "bill and hold" procedure.

With regard to the bill and hold sales, they argue that 4 of the 5 were "even more illusory," as they were made to entities related to Medstone (Gaines Hammond, a major shareholder, and General Electric, with whom Medstone had a distribution relationship). Moreover, they contend that the bill and hold sale practice as well as the saturation of the renal (kidney) market for lithotripters had to be disclosed under 17 C.F.R. § 229.303(a)(3)(ii), since they constituted "known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations."

In addition, plaintiffs argue that this statement is misleading because it does not indicate that 11 of these 19 "shipments" were to gallstone clinical evaluation sites, and therefore did not reflect a recurring set of sales. Plaintiffs charge that defendants' omission of the fact that these 11 shipments were not part of an upward trend in lithotripter sales is actionable.

Defendants argue that the statement is true because the 5 bill and hold sales were indeed shipped — to offsite storage areas until the buyers requested delivery. Defendants support the use of the bill and hold sale revenue recognition procedure with a memo prepared by Medstone's accountants at Arthur Young, which analyzes and approves the use of the procedure under the circumstances (Ex. 1010). The Arthur Young memo was communicated to Medstone prior to the release of the statement at issue (Radlinski decl. ¶ 2).

Moreover, defendants point out that the purchasers of the shipments were identified in the 1988 10-K form, i.e., "eleven systems to U.S. customers under the Company's IND/IDE for gallstone treatments" (these were the gallstone clinical programs; the 10-K indicates elsewhere that an IND/IDE is a provisional permit issued to devices by the FDA so that they may undergo

clinical trials) and "Dr. Gaines Hammond, a stockholder of the company . . . the Company sold one system to Dr. Hammond and two Systems to a company controlled by Dr. Hammond." Ex. 368 at 14-15, 4. Plaintiffs' contention that defendants' statement with regard to the increased sales revenue was misleading because it failed to identify purchasers is not well-taken in light of these disclosures.

Finally, defendants contend that the bill and hold revenue recognition policy did not constitute a "known trend or uncertainty" which had to be disclosed, since it was a procedure being properly utilized in accordance with SEC guidelines. Defendants respond to plaintiffs' main point: the company was not required to disclose a practice which clearly met GAAP and SEC standards so that revenue recognition was proper.

In reply, plaintiffs contend that: (1) defendants' "shipped" distinction is one without a difference, since customers did not actually receive them; and (2) the inclusion of the 5 bill and hold sales inappropriately indicated a larger upward swing in sales than actually occurred, absent disclosure of the bill and hold sale procedure's usage.

Although the careful use of the word "shipments" juxtaposed with the words "increase in sales revenue" could create the misleading impression that the shipments were effected upon completely paid purchases, the falsity of this statement would present a genuine issue of material fact for trial. Accordingly, the Court would deny plaintiffs' motion for summary adjudication as to it.

c. March 15, 1989 newspaper article: Radlinski's statement that "in April 1988, the Company von final (renal] approval' by the FDA, clearing the way for the sale of 19 lithotripters . . . . [in 1988]" (Ex 227)

Plaintiffs argue that this statement is false and misleading because it portrays the sales as a direct consequence of the FDA renal approval, when in fact eleven of the sales we're to clinical sites in the biliary studies (which would have occurred independent of FDA approval of the machine's usage for renal treatments). Defendants counter that the statement indicates FDA

approval for renal usage was only one factor in pushing the sales, and that FDA renal approval was also a driving force in the eleven biliary sales, since many potential biliary test centers were waiting for FDA renal approval before purchasing them for gallstone trials. (Mark Cherney decl.) Moreover, defendants add that the March 1989 Form 10-K with the breakdown of the sales had been issued already, so that this April 1989 statement was not misleading in the context of that information.

Plaintiffs argue in reply that Cherney's declaration is useless, since he does not indicate how he knows that "some" of the biliary test sites waited for FDA renal approval before purchasing the lithotripter for biliary studies. They also contend that the "benign" breakdown of sales in the Form 10-K cannot counteract the misleading nature of this statement standing alone.

In order to prevail, plaintiffs "must demonstrate that [the] particular statement, when read in light of all the information then available to the market, or a failure to disclose particular information, conveyed a false or misleading impression." *In re Convergent Technologies Securities Litigation*, 948 F.2d 507, 512 (9th Cir. 1991). Plaintiffs have not met their burden with respect to this statement. Whether the statement overshadows the previously released sales breakdown, thereby allowing a misleading implication that lithotripsy sales would increase markedly upon FDA approval, is a question of fact. Accordingly, the Court would deny plaintiffs summary adjudication as to the falsity of this statement.

d. Medstone's 1988 Form 10-K, published March 1989: "revenues are recognized for financial accounting purposes in accordance with the underlying contractual terms of each sale. Typically, revenue recognition requires the transfer of title upon shipment, customer acceptance, receipt of specified down payments and performance of all significant contractual obligations." (Ex 368 at 29)

Plaintiffs argue that this is misleading and false because the company in fact had no formal revenue recognition policy and the company did not even "typically" follow the procedure described in the statement itself. (Ex 1013 — Arthur Young memo to

Medstone indicating that a formal revenue recognition policy should be established). Defendants counter that this statement is not false at all because the statement does not indicate that the described procedures are the only ones followed by the company, and the statement itself discloses that revenue is recognized according to the terms in underlying contracts. Defendants point out that all of the bill and hold sales were conducted in accordance with underlying contractual terms. (Ex 1010 — Arthur Young memo indicating that all bill and hold shipments had contracts specifying bill and hold usage).

The Court would deny summary adjudication with regard to this statement, since the statement itself discloses the various transaction structures used by defendants.

e. April 25, 1989 Press release: "depending on the size and number of the stones, fragmentation rates as high as 97% and stone-free results of 90% were achieved at six months following treatment." (Ex 116)

Plaintiffs argue that this is false and misleading because: (1) defendants only indicated later, in the middle of the release that these figures were found "in patients with solitary gallstones less than 2 cm ... in diameter;" and (2) one day previously, defendants had provided the FDA with an update on their clinical trials, which indicated that only 33% of all patients with stones less than 2 cm in diameter and 48% of patients with solitary stones were rendered stone-free by the process (Ex 52). Plaintiffs also cite to the ever-gloomier statistics from the later stages of clinical trials, but these are irrelevant to the Court's determination of the statement's falsity *at the time it was made.*

Defendants counter that plaintiffs have taken this statement out of context. The full sentence reads: "depending on the size and number of the stones, fragmentation rates as high as 97% and stone-free results of 90% were achieved at six months following treatment." (Only 15% of the clinical subjects had reached the six-month point at that time.) Furthermore, defendants point out that the calculations submitted to the FDA were based on life table estimates, rather than actual cumulative observation data as the press release figures were.

In reply, plaintiffs argue that the statement is misleading because (1) it is based on such a small sampling, a practice which is known to produce unreliable scientific results and (2) the release downplays the fact that it is based on such a small statistical sampling.

The Court would deny summary adjudication here. The statement does not appear misleading, since it indicates that the test results are based on a small sampling and that "gallstone lithotripsy is still under clinical evaluation." Moreover, the very sentence reporting the results indicates that they vary with the number and size of stones involved.

f. May 2, 1989 Press release: "[t]he financial results for the first quarter were below plan, but we see increased sales activity compared to the fourth quarter of 1988. The market is responding favorably to Medstone's dual imaging therapy system (which treats both kidney and gallstones in one machine]." (Ex 118)

Plaintiffs argue that the statement regarding increased sales activity and the market's favorable response was false, in light of both the growing information that biliary lithotripsy was not so efficacious and the saturation of the renal lithotripsy market. To support their argument, they point to: (1) the bill and hold sale practices, which "puffed" sales revenues; (2) the May 1989 VP of Marketing Mesenbrink "overview" document (Ex 282), which stated that "[m]ost hospitals cannot justify purchasing a 'renal only' machine due to competition and that Medstone Marketing held the "opinion that big future sales of biliary machines will be severely compromised if the equipment does not treat patients more effectively ... [we should take steps] to increase the effectiveness before the marketplace (especially surgeons) becomes aware of the limitations;" and (3) the May 12 1989 written conclusions of Goodrich (Executive Vice President of Medstone Operations), which indicate that the total biliary market could support 80 to 160 lithotripters, with 40 already in place at clinical IDE test sites (Ex 170). Plaintiffs contend that in light of all this information which indicated that the market for biliary lithotripters was not as large as previously expected, and the realization that the clinical results were suffering a downturn, defendants should not have issued such an optimistic press release.

Defendants counter that (1) the statement is not forward-looking, but a reflection on the results from the first quarter of 1989 and (2) the "renal only machine" comment in the Mesenbrink report is inapposite to Medstone's machine, since it has dual renal and biliary capabilities.

In reply, plaintiffs argue that the statement is a forward-looking projection of sales, not a historical one, and defendants failed to fulfill their continuing duty to correct the press release as new information came in. They cite no caselaw for this latter proposition. However, they aptly point out the flaws in defendants' argument regarding the dual capacity of their lithotripter: the Medstone lithotripter would only be a renal lithotripter if FDA gallstone approval did not materialize, and Medstone would' become mired in the competitive "renal only" market.

This circuit has rejected the concept of a "duty to continually inform" espoused by plaintiffs. *See Convergent*, 948 F.2d at 516. Moreover, the statement is not rendered false by its omission of these reports, since it merely talks about the present state of affairs and the market response at the time. In that context, defendants need not have disclosed the suspected future impact of the newer clinical trials in order to render the statement not misleading. Accordingly, the Court would deny Oplaintiffs summary adjudication as to the falsity of this statement.

g. November 15, 1988 Weeden Research report: "Overseas opportunities could dwarf the U.S. market." (Ex 131 at 16)

Plaintiffs contend that this was demonstrably false at the time it was made, as demonstrated by the deposition testimony of Dan Clark, Medstone's former Vice President of International Sales, in which he indicated that with regard to "[t]he total potential market for units to be sold by everybody, not just Medstone . . . whatever the U. S. market is, the worldwide market is usually equal." (Defendants Ex 1757). They also point to the June 19, 1989 notes of Mike Mesenbrink from a Medstone staff meeting, which indicate that (apparently according to Dan Clark), there was "good potential for the overseas market to equal 100% U.S. market." (Plaintiffs' Ex. 1020.) From this, plaintiffs argue that the Weeden statement was false in claiming that the US market

would be "dwarfed;" instead, it should have stated that the US market and worldwide market would be equal.

Defendants counter that the Weeden statement concerns Medstone's opportunities overseas, whereas the Clark deposition focused on the total potential market for all companies.

Plaintiffs have provided no evidence that at the time this statement was made, it was demonstrably false. The Clark deposition does not indicate at what point in time Clark meant to estimate the ratio of the overseas market to the U.S. market. Moreover, the Mesenbrink notes are from a June 1989 staff meeting — months after the Weeden report statement was made. Accordingly, the Court would deny summary adjudication as to this statement's falsity.

h. November 15, 1988 Weeden Report: "Medstone sold its first PMA (final FDA approval] renal lithotripter in the second quarter of 1988 and since then such sales have improved dramatically." (Ex 131 at 16)

This statement is false and misleading, plaintiffs argue, because there had been no increase in lithotripter sales for renal purposes. Plaintiffs produce the testimony of Peck Hayne, a stockbroker, who stated that in a May 3, 1989 conversation with defendant Errol Payne, Payne told Peck that "nobody was selling kidney stone machines for the past two years ..." (Ex 380 at 17). Moreover, plaintiffs point to defendant Rose's own handwritten notes in response to the question "is the kidney machine market saturated?" where he inscribed "it's dead." (Defendants' Ex. 338).

Defendants counter that the statement is not misleading, in the context of a previous sentence in the preceding paragraph, which indicates that "[a]ll current Medstone sales, whether biliary IDE sites or renal PMA sites, are exactly the same machine capable of treating both kidney and gallstones." (Plaintiffs' Ex 131 at 16): Since the preceding sentence makes clear that the same machine is sold for both renal and biliary purposes, defendants contend that the statement at issue is neither false nor misleading. Moreover, defendants point out that sales for non-gallstone clinical sites amounted to three machines in the second and third quarters of 1988, which was a 3000 increase from the preceding year.

(Final FDA approval was only given in April 1988; the last previous permitted sale to a renal evaluation site occurred in 1987.)

Plaintiffs reply that, for all intents and purposes, defendants were selling a single-purpose (renal) lithotripter absent final FDA approval of the lithotripter's use for gallstones. Therefore, any of defendants' "dual machine" arguments are inapplicable.

This statement appears false and misleading since the "dramatic" increase was not necessarily due to (implied) market demand, but rather to the fact that the FDA would permit no sales between the time of the last clinical test site sale and final FDA approval. However, the Court would not conclude that this statement's falsity is established as a matter of law and would deny plaintiffs' motion.

i. November 15, 1988 Weeden report: "Demand for Medstone lithotripters is strong and growing."

Plaintiffs argue that this is misleading because, per defendant Rose's September 1988 notes, the renal lithotripsy market was "dead." Moreover, since FDA approval for gallstone use of the lithotripter was not yet certain, gallstone lithotripter demand could not be very strong. Defendants counter that Rose explained this handwritten statement in his deposition, remarking that "people were primarily interested in multi-purpose machines . . . Gave us a competitive advantage." (Defendants' Ex 1761). Defendants reiterate that the Medstone machine was dual purpose, not single purpose. Plaintiffs reply that, in reality, the Medstone lithotripter was single purpose since no FDA approval for widespread gallstone crushing use had been granted. Plaintiffs have a good argument here. At the time the statement was made, it is questionable whether there was any factual basis for the assertion.

j. November 15, 1988 Weeden report: "Re believe shockwave lithotripsy will not only replace a substantial number of gallbladder surgeries, but it will begin to be used to remove gallstones before the onset of serious problems . . . prospective [patient] population . . . will expand well beyond the potential 15 million known gall-

stone patients to include those seeking preventive treatment." (Ex 131 at 4)

Plaintiffs argue that this is misleading, drawing on the deposition testimony of their expert, Dr. Way, who stated that "[p]reventive treatment of gallstones by lithotripsy would never occur" (Way Tr. at 130-132; defs' ex. 1762) and the testimony of Laura Murphy, of Siemens Co., one of Medstone's competitors, who stated that the FDA "indicated to Siemens very clearly that asymptomatic patients were not appropriate for intervention." (Murphy Tr. at 77).

Defendants counter that this is a forward-looking statement which is not false if it is reasonable and made in good faith. *See In re Apple*, 886 F.2d at 1113. They argue that there was reason to believe that patients suffering from minor symptoms would be treatable with lithotripsy and that such sufferers do not constitute "asymptomatic" patients because asymptomatic patients would not seek treatment in the first place. They point to their expert Dr. O'Leary's deposition, in which he states that "[m]ost gallstones have some symptoms associated with them." (Defendants Ex 1760).

Defendants have pointed to evidence which would indicate that the statement had some factual support at the time it was made. Accordingly, the Court would deny plaintiffs' motion for summary adjudication of its falsity.

k. May 3, 1989 Weeden report: "Domestic sales progress is partially tied to the gallstone approval process at the FDA."

Plaintiffs counter that this was false, since sales were entirely linked with FDA approval of gallstone treatment, in light of the renal market being "dead," as defendant Rose characterized it in September 1988. Defendants counter that this is a true statement, since defendants still had the renal capacity. They also point to 6 lithotripter sales made since the FDA refused to approve the machine for gallstone purposes. (Radlinski decl.) Further, defendants indicate that they disclosed to the press on July 27, 1989 that "while prospective buyer interest is very high, we expect only moderate increases in out shipments" until the FDA positively

indicated that FDA gallstone approval was forthcoming. (Ex 307)

Although plaintiffs have produced evidence that the renal market was not faring well at the time this statement was made, a factual issue exists regarding its falsity. Accordingly, the Court would deny plaintiffs' motion as to this statement.

APPENDIX C

NOT FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

WILLIAM KAPLAN, *et al.*,
Plaintiffs-Appellants,
v.
FREEMAN ROSE, *et al.*,
Defendants-Appellees.

Nos. 92-55879,
92-56055
DC Nos. CV 89-740 AHS
CV 90-03 AHS

Before: BROWNING, BOOCHEVER, and KLEINFELD, Circuit Judges.

The panel has voted to deny the petition for rehearing. Judges Browning and Klenifeld reject the suggestion for rehearing en banc and Judge Boochever recommends rejection of the suggestion for rehearing en banc.

The full court has been advised of the suggestion for rehearing en banc and no active judge has requested a vote on whether to rehear the matter en banc. (Fed. R. App. P. 35.)

The petition for rehearing is denied and the suggestion for rehearing en banc is rejected.